Exhibit B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES ONLY TO: **THE WAVE 1 CASES IDENTIFIED IN EXHBIT A TO ETHICON'S MOTION**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' RESPONSE TO DEFENDANT'S MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY DR. DUNN PH.D.

Ethicon's Motion to Exclude the Opinions and Testimony of Dr. Russell Dunn, Ph.D., ("the Motion" or "Ethicon's Motion"), is fundamentally flawed in that it manipulates testimony to make it appear as though Dr. Dunn is not qualified, or that he otherwise does not have the requisite knowledge, to offer the product design and risk assessment opinions put forth in his report. On the contrary, Dr. Dunn is more than qualified to offer the opinions set forth in his Wave 1 report. Moreover, he relies upon not only his own vast experience, but also thousands of pages of Ethicon's internal documents, over 25 depositions (and exhibits thereto) of Ethicon employees involved in the design and launch of all of Ethicon's mesh products at issue, every internal polymer failure analysis study ever performed on anything made of Prolene (that has been produced), the design history files and technical files of all products involved in this litigation, and the ample, relevant peer-reviewed literature on polymer failure analysis and the principles of device design and risk analysis.[1]

[1] Ex. A, Dunn Report; *see also* Ex. D, Dunn Reliance List.

Ethicon's Motion expends a great deal of effort trying to make it appear as though Dr. Dunn did not review or rely on these materials to form his opinions—but this is simply not the case. Ethicon does not raise a single legitimate criticism of Dr. Dunn's opinions in these cases; instead, the arguments are based on a faulty understanding of medical device manufacturers' risk management systems and risk analyses. The Motion also spends most of its length cherry-picking out-of-context testimony and then twisting those statements to make it appear as though Dr. Dunn is unqualified and that his opinions are unsupported. At its core, Ethicon's arguments show a lack of understanding of the principles of device design and risk management, and how the relevant standards from the International Organization for Standardization ("ISO") are applied.

Dr. Dunn's opinions are separated into two sections: (1) Polymer Failure Opinions; and (2) Product Design Opinions.[2] His Polymer Failure Opinions are unchallenged, and there is no basis to exclude those opinions. Moreover, Dr. Dunn's opinions and methodology have not changed since he was vetted to testify by this Court in the *Huskey* litigation.[3] He should be allowed to testify in this Wave as well.

This Court has allowed the kind of expert testimony that Ethicon seeks to exclude here on several occasions.[4] This Court has routinely held that experts with qualifications similar to Dr. Dunn's are permitted to offer general causation opinions based upon: (1) the peer-reviewed scientific literature, (2) their education and experience, and (3) their review of SEM images and

[2] *See* Ex. A, Dunn Report
[3] *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 710-711 (S.D. W. Va. 2014).
[4] *See, e.g., Huskey*, 29 F. Supp. 3d 691; *Cisson v. C.R. Bard, Inc.*, No. 2:11-cv-00195 2013 U.S. Dist. LEXIS 149976, (S.D. W.V. Oct. 18, 2013); *Mathison* v. *Boston Sci. Corp.*, No. 2:13-cv-05851, 2015 U.S. Dist. LEXIS 59047 (S.D. W. Va. May 6, 2015).

other relevant evidence—and there is no reason why the Court should reverse its previous rulings (and the other progeny of *Daubert*) in the present case.[5]

STANDARD OF LAW

Under Rule 702 of the Federal Rules of Evidence, as interpreted by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), an expert witness may be qualified by "knowledge, skill, experience, training or education." Fed. R. Evid. 702. The witness's testimony also must represent "scientific knowledge," meaning that it is supported by appropriate validation; and it must assist the jury, meaning that it must be relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995).

The Court's focus in a *Daubert* inquiry should be solely on the expert's "principles and methodology, not on the conclusions that they generate." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Notably, "the Supreme Court itself viewed *Daubert* as a *liberalization*, not a tightening, of the rules controlling admission of expert testimony." *Cavallo v. Star Enterprise*, 100 F.3d 1150, 1158 (4th Cir. 1996) (emphasis added). Further, "exclusion is the least favored means of rendering questionable scientific evidence ineffective." *Id.*

ARGUMENT

I. DR. DUNN'S OPINIONS ARE RELEVANT AND RELIABLE

Ethicon's arguments to exclude the testimony of Dr. Dunn are not supported by any legal precedent, and are actually undermined by the prior ruling of this Court. Indeed, Dr. Dunn was vetted and allowed to testify in *Huskey*, where this Court held: "[an] expert's testimony must help the jury to 'understand the evidence or to determine a fact in issue.' Fed. R. Evid. 702. This testimony assists the jury in determining whether Ethicon was negligent in designing the TVT-O.

[5] *Id.*

Therefore, Ethicon's motion to exclude Dr. Dunn's risk assessment opinions is DENIED."[6] Dr. Dunn's opinions are similarly relevant to the ultimate question of liability that the jury will be asked to decide in these Wave cases; and they are reliably based in the scientific method and are otherwise sound under FRE 702 and *Daubert*.

1. Dr. Dunn is qualified to render his opinions.

a. Dr. Dunn is an expert in utilizing the FMEA, and his FMEA opinions are uncontested.

Ethicon repeatedly argues that Dr. Dunn is not qualified to offer opinions regarding its quality systems or its risk analyses for mesh products, but those arguments are fundamentally flawed.[7] Ethicon argues that Dr. Dunn must be an expert in biomaterials, medicine, pathology, and seemingly every other field that may have contributed to the design and quality systems for the meshes at issue.[8] But these arguments ignore the specific field of scientific inquiry where Dr. Dunn has expertise—and the field in which he offers opinions in these cases—product design. For example, Ethicon argues that Dr. Dunn would need to be an expert in biomaterials to opine on the mechanism by which Prolene oxidizes *inside the body*. But his expertise is in device design, and he is not testifying about how Prolene oxidizes inside the body—he is testifying that the Failure Modes and Effects Analysis ("FMEA") for the products in question are not being utilized correctly, and those opinions are not challenged. Dr. Dunn is unquestionably an expert in how devices are designed and how their safety is maintained with risk analyses as part of a larger risk management plan.

[6] *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 710 (S.D. W. Va. 2014).
[7] *See* Def's Motion, generally.
[8] Def's Motion at 2-4, 6, 8, 13, 14, 16, 17, and 20.

b. ISO 14971 is an international standard covering risk management for medical device manufacturers—and risk analysis, such as Ethicon's FMEA risk analysis is only one part of the risk management process.

Dr. Dunn explains in his report that every product manufacturer needs a risk management plan in place for every product sold.[9] ISO 14971 is an international standard that covers risk *management* for medical devices. *In part*, ISO 14971 describes standards for how a risk *analysis* for a medical device should be performed—but a risk analysis is only one component of a larger risk management plan.[10] It is the Standard Operating Procedure ("SOP") at Ethicon to utilize the FMEA risk analysis to assess, investigate, and mitigate every potential risk before (and after) any medical device is launched.[11] Dr. Dunn does not offer an opinion on every aspect of Ethicon's risk management plan under ISO 14971, but instead he only offers his opinion on whether Ethicon followed its FMEA risk analysis. Dr. Dunn's opinion is that Ethicon is not following the requirements of the FMEA risk analysis for the devices at issue, and because the FMEA is not being performed correctly, the requirements of the larger risk management plan are also not being satisfied.[12]

None of these facts are disputed in Ethicon's Motion; however, Plaintiffs' believe this clarification is necessary, as Ethicon's arguments seem to confuse the broader issue of risk *management* with Dr. Dunn's more specific opinions regarding FMEA risk *analysis*.

[9] Ex. A, Dunn Report at 21.
[10] *Id.*
[11] *Id.* at 19.
[12] To be clear, ISO 14971 provides standards for how to create and maintain a risk management plan specific to medical devices—and ISO 14971 also requires that a risk analysis be put in place for every medical device as part of a risk management plan. Ex. A, Dunn Report at 21. The FMEA is a mode of risk analysis that encompasses all of the standards imposed by ISO 10993—including the need to test for degradation and oxidation. *Id.* Dr. Dunn is an expert at applying and utilizing FMEAs and does not need to be an expert in biomaterials, medicine, pathology, or complaint handling to hold his opinions. *Id.*

c. The FMEA is the only risk analysis used at Ethicon and Dr. Dunn is an uncontested expert in utilizing it.

Ethicon's Motion ignores the fact that the SOP at Ethicon is to use the FMEA for every medical device that it produces, and that there is no other mode of risk analysis that Ethicon will use for its risk management. There is only the FMEA. Instead, Ethicon argues that the risk analysis standards outlined in ISO 10993 are controlling:

> ISO 14971 "specifically direct[s] that the reader refer to ISO 10993 for guidance on the general principles for biological evaluation, or biocompatibility, of medical devices. This expressly includes risk analysis concerning the "chemical nature of the materials" and the "influence of biodegradation."[13]

Yet the Motion acknowledges that the FMEA is a recommended mode for medical device risk analysis by ISO 14971:

> ISO 14971 defines a "risk analysis" as a "[s]ystematic use of available information to identify hazards and to estimate risk." Nowhere in ISO 14971 is there any requirement that risk analysis be documented in any particular format. Note 2 under Section 4.1 of ISO 14971 references merely as examples "some risk analysis techniques are described in Annex G." An FMEA format is but one of the sample techniques listed in Annex G.[14]

Ethicon's Motion misses the point of what product design entails—and what actually happens internally at Ethicon—which is to require that the FMEA is used to assess the risks associated with in all of its products.[15]

d. Dr. Dunn opines that the FMEA was not utilized properly for the devices at issue.

Dr. Dunn has opined that the FMEA was not properly used to identify or mitigate potential risks associated with Prolene's oxidation and degradation of the pelvic mesh products at issue.[16] The FMEA *requires* that every potential failure mode be described, investigated and

[13] Def's Motion at 4, citations omitted.
[14] Def's Motion at 8, citation omitted.
[15] Ex. A, Dunn Report at 19.
[16] *Id.*

mitigated, both before a product is launched and while it is on the market.[17] Under the rules for utilizing the FMEA risk analysis for medical devices, every potential failure mode is to be recorded in the FMEA and investigated, it is a living document.[18]

As Dr. Dunn explained, it is of no consequence if the medical device manufacturer *believes* if the failure mode will lead to clinical complications or not; the potential failure mode *must* be described in the FMEA, and then investigated, no matter what.[19] Oxidation of Prolene, however, is not described as a potential failure in any of the FMEA documents associated with the products at issue.[20] This is true despite the fact that the available literature states that polypropylene blends can oxidize and lose their mechanical properties, and Ethicon even performed several internal oxidation studies that concluded Prolene oxidizes and degrades after implantation.[21] As such, oxidation *should* be described in the FMEA, but it is not.[22] Indeed, if the FMEA had identified oxidation as a potential failure mode, the FMEA process would require that an investigation take place into how or if mesh oxidation can injure women implanted with these products.[23] And since the FMEA risk analysis portion of the larger risk management plan is not functioning as it should, the risk management plan is broken for the same reason.[24]

2. Dr. Dunn's oxidation-related opinions are within his area of expertise.

Dr. Dunn's opinions on the inherent chemical nature of polypropylene to oxidize, and on how Ethicon's devices were not designed with this fact in mind, are central to the jury understanding the defective nature of the products at issue. The science is sufficiently settled on

[17] *Id*. at 21-23.
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.* at 28-31.
[22] *Id.*
[23] *Id.*
[24] *Id.*

this issue, and it is not even challenged in Ethicon's Motion. Polypropylene must be stabilized against oxidation in order for it to have any use at all, and the Polymer Failure opinions offered by Dr. Dunn, which include his reliance on all of the internal oxidation studies performed, are not being challenged *at all* in Ethicon's Motion.

Instead, Ethicon only takes issue with Dr. Dunn's opinions on Product Design and Risk Analysis. And to be clear, Dr. Dunn's opinions on Product Design and Risk Assessment are, in part, based on what he has seen internally with regard to Prolene's *in vivo* oxidation studies as well as the specific findings and design activities taken by the Ethicon employees who developed these products.[25]

3. Ethicon's Motion is intentionally confusing and cumbersome.

Ethicon's Motion is almost entirely based on misleading statements and inaccurate paraphrasing of testimony that only serve to confuse the issues present. Fundamentally, all of Ethicon's complaints are grounds for cross-examination, not exclusion. *See In re: DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prods. Liab. Litig.*, No. 3:11-MD-2244-K 2014 U.S. Dist. LEXIS 97798, at *45 (N.D. Tex. July 18, 2014). But while Ethicon's contentions may be relevant for cross-examination, simply putting words into an expert's mouth is not a grounds for exclusion.

For example, Ethicon states: "Dr. Dunn admits that he is not qualified to opine whether Prolene does in fact undergo oxidative degradation in the body."[26] Dr. Dunn has never held himself out as being an expert about how the human body reacts with Prolene to oxidize it, but Dr. Dunn does make it clear in his report (and in the actual testimony cited by Ethicon) that he is an expert on polymer failure and analysis, as well as an expert on device design and risk

[25] Ex. A, Dunn Report at 19-30.
[26] Def's Motion at 3.

assessment.[27] As such, Dr. Dunn's opinions only focus on device design and polymer failure analysis. The Motion continues: "Dr. Dunn has no expertise relating to biocompatibility. In fact, he does not even know what a biocompatibility risk assessment is."[28] Again, Dr. Dunn has never held himself out as an expert in biocompatibility, specifically, and a biocompatibility risk assessment is only part of the larger framework of device design and risk assessment where Dr. Dunn has expertise. As he testified:

> Q. Have you considered any of Ethicon's biocompatibility risk assessments?
> A. Yes. I've looked at their biocompatibility testing. I've looked at a lot of their testing. I'm telling you they did not consider oxidative degradation in this risk analysis. And that's clearly evident by the listing of questions that I provided in my report.[29]

Ethicon's entire Motion is based on inconsistencies similar to what is described above. Plaintiffs will address each of the arguments below (in the order they are made in Ethicon's Motion), but Dr. Dunn's opinions are clearly stated in his report. And the documents, depositions, clinical literature and other support that he relied upon to form those opinions are also detailed therein. There is absolutely nothing in Ethicon's Motion that takes away the relevance and reliability of the opinions that Dr. Dunn has put forth for these Wave 1 cases.[30]

II. PLAINTIFFS' RESPONSE TO DEFENDANT'S ARGUMENTS

A. Dr. Dunn is qualified to render his opinions.

1. Dr. Dunn has the requisite knowledge to offer his opinions on device design and polymer failure analysis.

Ethicon misstates Dr. Dunn's opinions to fit the arguments made against him. He has not, and will not, provided an opinion as to how Ethicon's Prolene undergoes oxidation inside the body, but he is an expert in the same chemical analyses that Ethicon used internally to

[27] *Id.*
[28] *Id.*
[29] Ex. B, Dunn 03/2016 Deposition at 115:3-10.
[30] *See* Ex. A, Dunn Report, generally; *see also* Ex. D, Dunn Reliance List

conclude that Prolene degrades inside the body.[31] And while Ethicon is correct that it is Dr. Dunn's opinion that the use of Prolene in this application is the result of failures in the FMEA risk analysis and risk management plan,[32] Ethicon incorrectly states that Dr. Dunn does not have the requisite knowledge to assess the design and quality systems involved.[33]

As Dr. Dunn's report states: "[the SOP] at Ethicon is to employ a Failure Modes and Effects Analysis to assess and mitigate these potential risks before any product is launched and while it is on the market. This SOP was not followed properly with respect to the Prosima, Prolift and Prolift+M devices."[34] Ethicon does not question Dr. Dunn's expertise in dealing with FMEAs, nor does it deny that its SOP is to employ the FMEA as the mode of risk assessment for all of its products. The only question put forth is to his qualifications in regards to *performing the tests* required by the FMEA and, evidently, ISO 10993. But regardless of whether he is qualified to perform those tests, he still has expertise in both product design and in utilizing FMEAs.

2. The Ethicon FMEA risk analysis upon which Dr. Dunn opines comports with ISO 14971's requirements.

Ethicon argues that Dr. Dunn has never designed a medical device following ISO 14971 and ISO 10993, and that he did not follow these standards properly in making his assessment that oxidation and degradation were not considered in the development of the products at issue.[35] But as Dr. Dunn explained to defense counsel, everything in ISO 14971 and ISO 10993 regarding a consideration of biocompatibility and chemical degradation is addressed in the FMEA risk

[31] Def's Motion at 2; *see also* Ex. C, Dunn 11/2015 Deposition at 43:10-58:15; *see also* Ex. A, Dunn Report.
[32] *Id.*
[33] Def's Motion at 3-4.
[34] Ex. A, Dunn Report at 19.
[35] Def's Motion at 4-5.

analysis.[36] There is no need for Dr. Dunn to return to the ISO standards to form his opinions because those standards specifically state that the FMEA contains everything that a medical device risk analysis needs. As his report states:

> Ethicon uses the recommendations in ISO 14971 as guidance for its risk analysis for medical devices, including the use of the failure mode and effects analysis, but the use of the FMEA is also mandated by internal SOP to provide a "methodology for evaluating and analyzing risks resulting from potential failure modes, with the objective of eliminating or minimizing these risks to an acceptable level with the current state of technology."[37]

Moreover, Ethicon's argument that Dr. Dunn needs to be an expert in medical device design or biocompatibility to offer his opinions has no merit. ISO 14971 is an international standard that describes how to perform a risk analysis on a medical device—but there are many modes of risk analyses—and one way is to use the FMEA. If Ethicon had chosen *another* risk analysis besides the FMEA—one that was somehow specific to medical device design—then Ethicon's arguments may have had some merit. But Ethicon's internal SOP *mandates* that the FMEA is the risk analysis to be used for all of the devices it sells. This is exactly the area where Dr. Dunn has extensive experience and expertise, and his testimony should not be excluded.

3. Dr. Dunn is qualified to opine on the deficiencies in Ethicon's quality systems because they are due to failures in the FMEA.

Ethicon points out that Dr. Dunn opines that there are no defined or written standards when it comes to addressing quality systems for the design of medical devices.[38] Dr. Dunn is not only correct on this point, he explained why at his deposition; namely: because every medical device manufacturer is different, there is no way to control the SOP of every manufacturer, and instead only guidelines are provided.[39] Moreover, his opinion is supported by the Code of

[36] Ex. C, Dunn 11/2015 Deposition at 186:9-23.
[37] Ex. A, Dunn Report at 21.
[38] Def's Motion at 6.
[39] Ex. C, Dunn 11/2015 Deposition at 19:12-22:4.

Federal Regulations ("CFR") (cited to in Ethicon's Motion)[40]—which does not lay out any specific standards in regards to how a quality system should be implemented. Instead, the CFR only states what a quality system should entail, and nothing detailing the day-to-day operations of the quality system is described.[41]

As previously explained, however, Ethicon internally *mandates* that the FMEA risk analysis is used with all of the products that it sells. And the FMEA requires that Ethicon take all of the available information from the field about potential failure modes and then apply them back into to the FMEA, making it a living document.[42] For decades, the literature has reported oxidation and degradation for polypropylene materials—*and* Ethicon has confirmed that Prolene oxidizes and degrades *in vivo*—yet, to this day, the FMEA for the devices at issue have no mention of an oxidation failure mode.[43] Dr. Dunn's opinions on Ethicon's quality systems being deficient are clearly relevant and reliable, and they should not be excluded.

4. Dr. Dunn is an expert on the FMEA and on analyzing polymer failure modes, not biocompatibility.

Ethicon also repeatedly argues that Dr. Dunn needs to be a biomaterials expert to opine about device design, but that is not the case where he is not providing a biomaterials opinion. Dr. Dunn does not need to be an expert in biocompatibility to assess if Ethicon is properly utilizing the FMEA. As stated above (and in his report), it is Dr. Dunn's opinion that the information from the field regarding an oxidative failure mode was never taken into account in

[40] Def's Motion at 6.
[41] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=820&showFR=1&subpartNode=21:8.0.1.1.12.2 (last accessed 5/8/16).
[42] Ex. A, Dunn Report at 30-31.
[43] *Id.*

the FMEA for these products—and that if Ethicon ever had, they would have found another suitable material for this application.[44]

B. Dr. Dunn's opinions are reliable.

1. Dr. Dunn is qualified to offer his criticisms of the FMEA utilized for these products.

a. Ethicon SOP mandates the FMEA be used.

Ethicon's argument that Dr. Dunn misapplied ISO 14971 is wrong.[45] In fact, it is Ethicon who misconstrues ISO 14971 in its Motion. As explained above, and as discussed in Dr. Dunn's report, ISO 14971 is an international standard for how to create and maintain a risk management plan for medical devices. ISO 14971 is an international standard, not a kind of risk analysis or risk management plan. Ethicon has its own risk management plan in place—which seeks to comport with the international standard—and part of that plan is to utilize the FMEA as its mode of risk analysis for each of its products. These facts are never challenged in Ethicon's Motion.

b. **The FMEA was not properly utilized in the products at issue.**

Ethicon next asserts that because Dr. Dunn misapplies ISO 14971, he refuses to go beyond the FMEA, and he ignores the biocompatibility analyses performed on the products at issue.[46] Again, Ethicon's arguments on this point are either misdirection, or they are simply mistaken. ISO 14971 is a guideline for what any risk management plan must contain, including a medical device risk analysis. The FMEA is a risk analysis that comports with everything that ISO 14971 requires. And the FMEA is the risk analysis that Ethicon *mandates* be used in all of its products. Any argument that Dr. Dunn's opinions are invalid because he is following the

[44] Def's Motion at 8-9; *see also* Ex. A, Dunn Report.
[45] Def's Motion at 8-11.
[46] *Id*. at 12-14

FMEA, *which is Ethicon's chosen risk analysis that comports with ISO 14971*, is at odds with itself.

2. Dr. Dunn does not agree that additional oxidation testing of Prolene mesh should have been skipped because ISO 14971 and 10993 caution that unnecessary testing should be avoided.

Ethicon asserts that it did not need to test if or how Prolene's *in-vivo* oxidation would harm women implanted with vaginal mesh. In doing so, however, Ethicon is simply disagreeing with, and not undermining the scientific reliability of, Dr. Dunn's opinions. Dr. Dunn fully agrees with every recommendation stated in ISO 14971, but Ethicon's arguments fail to grasp the concept that the FMEA comports with every standard for a medical device risk analysis that is described in ISO 14971—which includes the need for any biocompatibility testing or analysis described in ISO 10993.[47]

What Dr. Dunn disagrees with is Ethicon's argument that the Prolene meshes used in these pelvic applications did not need further testing after Ethicon found oxidative degradation occurring on Prolene *in vivo*.[48] Ethicon argues that these ISO standards "caution that unnecessary testing should be avoided"—but Ethicon is perfectly willing to implant these pelvic mesh products without understanding the effect that oxidative degradation has inside the female pelvis.[49] All of Dr. Dunn's well-supported opinions are in direct opposition to that argument. And itis not the Court's role on a *Daubert* motion to determine which side is correct. *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999).

[47] *See* Def's Motion, generally.
[48] Ex. A, Dunn Report at 19.
[49] Def's' Motion at 15.

3. Dr. Dunn is not a medical doctor, and he is not trying to associate clinical harm with Prolene's *in vivo* oxidation.

Ethicon's argument that Dr. Dunn is not qualified to testify regarding the clinical complications associated with the Prolene in Ethicon's mesh products seeks to confuse the issues in this case. Dr. Dunn does not provide any opinions on the clinical harm of the oxidative process, or the results of the degradation process *in vivo*.[50] Dr. Dunn will defer to other experts to speak to the clinical complications of Prolene oxidation and degradation inside the body.

4. Dr. Dunn is not a biomaterials expert.

Similarly, as explained above, Dr. Dunn has not and will not hold himself out as a biomaterials expert who is capable of testifying about how the body reacts with and oxidizes Prolene meshes.

5. ISO 14971 is a standard not a mode of risk analysis.

As explained above, ISO 14971 is an international standard that describes how to create and maintain a risk management plan for medical device manufacturers, including the requirement that every medical device have a risk analysis to maintain its safety, Ethicon mandates that the FMEA be used for its risk management plan to properly function. Dr. Dunn is an expert on device design, risk management, and risk analysis—those opinions are never questioned in Ethicon's Motion. Instead, Ethicon argues that Dr. Dunn should have assessed the risk/benefit analyses for these products to properly assess the health of its risk management plan.[51] And although Ethicon is correct that a risk/benefit analysis is part of a risk management plan, the point has nothing to do with the issues present. Dr. Dunn's opinions are focused on how the FMEA risk analyses were not properly utilized and because of that, the risk management plan is not properly functioning.

[50] *See* Ex. A, Dunn report, generally.
[51] Def's Motion at 19.

C. Dr. Dunn's opinions are not unfairly prejudicial.

As explained above, in *Huskey*, this Court held that an "expert's testimony must help the jury to 'understand the evidence or to determine a fact in issue.' Fed. R. Evid. 702. This testimony assists the jury in determining whether Ethicon was negligent in designing the TVT-O. Therefore, Ethicon's motion to exclude Dr. Dunn's risk assessment opinions is DENIED."[52]

In an attempt to counter-act this established probative value, Ethicon simply argues that Dr. Dunn is wrong about the occurrence of oxidative degradation, and that he has not studied how much time it takes to occur.[53] First, Ethicon's assertion that Dr. Dunn is wrong, and oxidative degradation simply does not occur, is not the type of question that the Court should answer on a Daubert motion. *Westberry*,, 178 F.3d at 261. Second, with regard to the timing of that oxidative degradation, that question is, at best, a subject of cross-examination—it does not require the exclusion of Dr. Dunn's opinions. *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972 2014 U.S. Dist. LEXIS 92316, 4 (S.D. W. Va. July 8, 2014); *see also Pugh*, 361 Fed. Appx. at 456 (Any weaknesses in the underpinnings of an expert's opinion go to the opinion's weight, rather than its admissibility). As such, neither of these arguments raise the type of "unfair prejudice" that would call for the exclusion of Dr. Dunn's opinions under Rule 403.

D. Dr. Dunn will not testify about Ethicon's state of mind.

Ethicon correctly points out that this Court has previously excluded expert testimony regarding a corporation's knowledge or state of mind.[54] Dr. Dunn does not intend to do so in these cases. However, as this Court has previously ruled: "an expert may testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his or her

[52] *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 710-711 (S.D. W. Va. 2014).
[53] Def's Motion at 19-20.
[54] Def's Motion at 13-14.

opinions."[55] Dr. Dunn only intends to testify as to Ethicon corporate documents at trial for the purpose of explaining how the results of Ethicon's internal studies are consistent with his opinions in this case.

CONCLUSION

For the reasons stated herein, Plaintiffs respectfully request that the Court DENY Ethicon's Motion to Exclude the Testimony of Dr. Russell Dunn in its entirety.

This 9th Day of May, 2016 By: /s/ Michael H. Bowman

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[55] *Huskey v. Ethicon., Inc.*, 29 F. Supp. 3d 691, 702-703 (S.D. W. Va. 2014).

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CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2016 I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive services in this MDL.

By: /s/ Michael H. Bowman

EXHIBIT A

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO WAVE 1 CASES**	**Master File No. 2:12-MD-02327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

EXPERT REPORT OF POLYMER CHEMICAL TECHNOLOGIES, LLC OF

DR. RUSSELL DUNN, M.S., Ph.D., P.E.

I. QUALIFICATIONS

Russell F. Dunn, Ph.D. P.E.

I received my Bachelor's and Master's degree in chemical engineering from Auburn University in 1984 and 1988 respectively and my Ph.D. in chemical engineering from Auburn University in 1994. I wrote my dissertation on the Synthesis of Optimal Heat-Induced and Energy-Induced Separation Networks for Waste Minimization. I have been a Registered Professional Engineer in the State of Florida since 2003.

I am the President and Founder of Polymer Chemical Technologies, LLC, which I formed in 2004. Through this company I have been involved in well over 140 projects focusing on process and product design issues, process and product safety and polymer product analysis. I have also established a polymer analysis lab through this company. I have written in excess of 200 technical reports on polymer failure analysis and product and process design through this company in response to client needs and several of these reports were studies of polypropylene-based products. Many of these technical reports have included an assessment of the safety analysis that was conducted be the manufacture on their product design. Much of the work conducted through Polymer Chemical Technologies to date addresses design issues for large chemical and polymer manufacturing clients.

Prior to founding Polymer Chemical Technologies, I worked as a Chemical Engineering Consultant for McSwain Engineering, Inc. for three years, and prior to that I worked at Solutia, formerly Monsanto Chemical Company from 1995 to 2001. At Monsanto I was a Research Specialist, specializing in Nylon Plastics, Polymer and Industrial Fibers technologies, a Senior Research Specialist and Research Team Leader in Nylon Plastics Technology and, finally, I was a Science Fellow and Research Team Leader. I also worked to Ampex Corporation from 1985-1989 where I was a Manufacturing Manager for three years and a Senior Engineer/Staff Engineer in Process and Product Development.

My academic appointments and teaching experience includes, Professor of the Practice in the Department of Chemical and Biomolecular Engineering at Vanderbilt University since 2011. At Vanderbilt, I co-teach three courses on Product and Process Design as well as two laboratory courses on Chemical Engineering Unit Operations. The design and laboratory courses include instruction on the entire design process, including instruction in Risk Analysis, Hazard and Operability Analysis (HAZOP) and Failure Mode and Effects Analysis (FMEA) with an emphasis on safe design. I am one of 2 design professors in the Chemical Engineering Department at Vanderbilt and I have recently established the Chemical Engineering Process Innovation Center at Vanderbilt that is a combined process and product laboratory facility along with a state-of-the-art design instruction facility where design, analysis, operation, and safety are all addressed throughout the chemical engineering students' junior and senior year of course instruction. I was an adjunct professor with the Department of Chemistry at the University of West Florida in 2006 where I taught one course in chemistry and two chemistry lab courses. In 2000, I developed and taught a Ph.D. course on process integration design at the Technical University of Denmark to a class of 20 doctoral engineering students from around the world. From 1990-1995, I was a Chemical Engineering Faculty Member at Auburn University, where I taught undergraduate courses in chemical engineering on Material Energy Balances and three chemical engineering laboratory courses.

I am author of numerous peer reviewed articles and book chapters regarding a variety of topics related to chemical engineering and materials science. I have taught courses on "*Nylon 6,6 Plastics and Polymers: Chemistry and Process Fundamentals," "Process Integration Technology for CLEANER Production: A Short Course on Energy Conservation and Waste Reduction Process Design, " "Process Integration Design Tools for Wastewater Reduction and Water Conservation in Chemical Process Industries," "Pollution Prevention through Process Integration," "An Introduction to Energy Integration Using Pinch Technology and Other Techniques," and "Optimal Design and Assessment of Waste-Management Processes.*" I have also co-authored two presentations on polypropylene transvaginal mesh: "Oxidation and Degradation of Polypropylene Transvaginal Mesh", at the IUGA 2015 Annual Conference in Nice France and "Failure Analysis of Transvaginal Mesh Products – a Biomaterials Perspective Using Materials Science Fundamentals at the American Institute of Chemical Engineers 2014 Annual Meeting in Atlanta.

Specifically, my expertise (skill, knowledge, training, education, and experience) are applied in the follow key areas that are *reliable* and *relevant* to this case:

Polymer Product Design, Manufacturing and Analysis Expertise

- Have for worked full-time for major polymer manufacturers, including General Electric and Monsanto Chemical Company.
- Have worked as a design consultant to the chemical and polymer industry since establishing my company in 2004 and clients have included DuPont, Westlake Chemical, Ascend Performance Materials, Sabic Innovative Plastics, Celanese, Cerex Advanced Fabrics, Solutia, and others.
- Have taught and am currently teaching polymer product safety case studies (both medical and non-medical products) and safety analysis techniques, including FMEA, at Vanderbilt University.
- Instruct and grade multiple groups' FMEA of chemical products and processes over the past 5 years at Vanderbilt University.

Risk Assessment Expertise, including Failure Mode and Effects Analysis

- Led multi-functional industrial teams (over 60 managers, engineers, chemists, etc.) to identify the root cause of failure of entire polymer product line and authored the overall technical report.
- Have taught and am currently teaching polymer product safety case studies and safety analysis techniques, including FMEA, at Vanderbilt University.
- Instruct and grade multiple groups' FMEA of chemical products and processes over the past 5 years at Vanderbilt University.

Polymer Product Failure Analysis Expertise:

- Have applied the use of *microscopic* (*e.g.* Scanning Electron Microscopy), *chemical analysis* (*e.g.* Fourier Transform Infrared Spectroscopy) and *thermal analysis* (*e.g.* Differential Scanning Calorimetry) techniques for the identification of the root cause of polymer product failure for hundreds of polymer products/designs and have provided over 200 technical reports on polymer failure analysis.
- Have significant prior experience analyzing polypropylene product failures for many applications; these include polypropylene fibers woven into straps used as a support harness in commercially available deer stand kits, its use in child car seat components, in automotive speaker grills, in plastic chairs, and many other polymer products where the use of plastic is required.

The expertise listed above is relevant to all polymer products, whether they are used in any application, including medical ones where it is used as an implantable device or for single-use products like syringes. My experience, education and training and a complete list of my published articles are more fully summarized in my Curriculum Vitae attached to this report at Exhibit A.

II. BACKGROUND

This report is an examination and assessment of the facts surrounding the Prolene-based pelvic mesh sold by Ethicon. In the course of my work, I analyzed and reviewed numerous depositions, exhibits, expert reports and discovery documents that were provided by counsel and at my request. These depositions, exhibits and discovery documents are identified in several indices at the end of this report.

The opinions expressed in this report are twofold. First, I present my opinions that were formed through using several industry standard polymer failure analyses, examining the use of Ethicon's polypropylene (PP) blend, Prolene, in the pelvic mesh application. Second, I present my opinions that were formed by utilizing several well-recognized product design methodologies, hazard control hierarchy and risk management principles and standards for Ethicon's Pelvic Organ Prolapse (POP) meshes utilized in the Prolift, Prolift +M, and Prosima devices.

Companies that manufacture all kinds of products, including Ethicon who manufactures medical devices, recognize both the need for and use of these kinds of analyses when designing products and performing risk management activities.

All of the opinions presented in this report focus only on the on the mesh utilized in Ethicon's Prolene-based pelvic mesh devices and they are presented to a reasonable degree of scientific certainty and within my fields of expertise. The Prolene-based mesh utilized in Ethicon's pelvic mesh devices is intended to be permanently implanted in a human body. As such, the mesh must be engineered to be as robust as possible for its intended purpose. In this report, I examine the fundamental flaws associated with the mesh's design.

III. SUMMARY OF POLYMER FAILURE OPINIONS

1) It has been well known for many decades that all forms of PP are highly susceptible to oxidation caused by the presence of a tertiary hydrogen on the polymer's chain. Oxidation and degradation of Ethicon's Prolene polypropylene is no exception. The addition of antioxidants to the Prolene blend only prolongs the time to oxidize and degrade the underlying PP, and it cannot be considered inert.

2) The failure analysis of medical polymers is included within the larger framework of the failure analysis of all polymers. The primary root cause of failure for PP used in medical products is oxidative degradation, leading to chain scission, embrittlement and ultimate failure.

3) Oxidative degradation and failure of PP components has been observed and published about since the polymer was first discovered. Knowledge of these failures should have been extended when considering the use of PP in any medical product, especially one intended to be implanted for the lifetime of a patient.

4) Ethicon scientists applied several polymer failure analysis methodologies on Prolene fibers that included numerous forms of standard polymer testing that are part of my expertise (scanning electron microscopy, chemical analysis and thermal analysis). Those scientists concluded numerous times, and beginning in the 1980's, that the root cause of cracked and degraded Prolene fibers was oxidative changes that were occurring *in vivo.* Additional polymer failure analyses were not performed to study any potential for injury that stemmed from using Prolene as a base for their pelvic mesh products, despite the knowledge that these *in vivo* changes were apparent.

5) External consultants hired by Ethicon reported that oxidative degradation was a likely cause of polymer failure in its mesh devices in 2011. This external review occurred over two decades after Ethicon's internal studies concluded that Prolene fibers were degrading inside the body.

6) The Prolene PP mesh used in Ethicon's pelvic mesh products is highly susceptible to oxidation and is, thus, prone to degradation after oxidation. Identification of the oxidative degradation defect in Prolene was both foreseeable and avoidable.

IV. POLYMER FAILURE OPINIONS

1.0 Polypropylene

1.1 Overview of Polypropylene

Polypropylene (PP) is a polymer that was introduced in the late 1950s. Polypropylene flakes and chips are generally manufactured from propylene gas, a component of natural gas. Polypropylene is generally formed by an addition reaction of the monomer propylene into polymers. After this polymerization occurs the fiber is typically melt-spun as filaments, where a single fiber strand is referred to as a monofilament.[1] The principle chemical structure of the polypropylene formed during this process is called "isotactic polypropylene" and it is shown below in Figure 1.

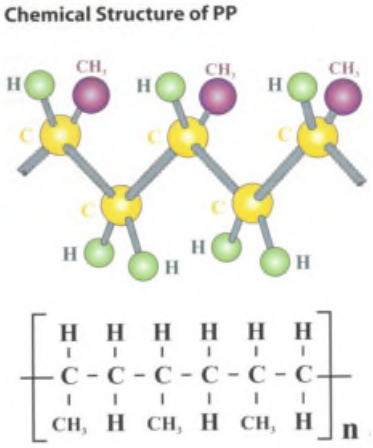

Figure 1. Polypropylene Chemical Structure[1]

1.2 Modifications to Polypropylene

1.2.1 General Modifications Made to Polypropylene

Different polypropylene grades within each classification are available, and can be chosen dependent on the application and processing method. It is possible to tailor grades of polypropylene with specific molecular properties and additives during manufacturing or during the extrusion part of the melt spinning process. Some examples of additives often incorporated into polypropylene include antioxidants, neutralizing agents, antistatic agents, slip agents and UV stabilizers.[1] For example, antistatic additives can be added to help polypropylene surfaces resist dust and dirt. It is in this sense that the intended use of the polymer becomes critical; the more a manufacturer knows about the intended environment, the more a manufacturer can do to prolong the properties that the polymer is desired to keep.

1.2.1 Ethicon Prolene Polypropylene

Ethicon sells permanently implantable polypropylene-based meshes intended to treat Stress Urinary Incontinence ("SUI") and Pelvic Organ Prolapse ("POP"). The Prolene-based mesh, used as a component in Ethicon's devices to treat POP, that was examined for this report was made from using Ethicon's Prolene resin.

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[1] Industrial Polymers, 2008, p. 74.
[2] Industrial Polymers, 2008, p. 74.

Prolene is Ethicon's proprietary blend of polypropylene that was originally developed for use as a suture material in the 1960's; it contains two antioxidants, Dilauralthiodipropionate (DLTDP) and Santonox R (which is a phenol)[2]. In addition, Prolene contains two lubricant additives and a colorant to enhance visibility.

1.3 Degradation of Polypropylene

All forms of PP are susceptible to oxidation (degradation) as shown in Table 1.[3] In fact, PP is reported to have the highest tendency for oxidative degradation when compared to other common commodity polymers as shown in Figure 2.[4]

Degradation of polypropylene occurs when the polymer is placed under certain kinds stress; these stresses can be environmental factors such as heat, light or mechanical influences, or these stresses can be more chemical in nature and take the form of acids, alkalis, or other oxidative species. The effect of these stresses can include the loss of tensile strength, changes to the appearance of the surface of the fibers, the polymer's color, and/or its shape. This degradation can be observed chemically by the appearance of hydroxyl and/or carbonyl bonds on the polypropylene that can be identified by the use of FTIR spectroscopy and/or X-ray photoelectron spectroscopy.[5]

[2] Eth.Mesh.02268619
[3] Applied Plastics Engineering Handbook, Processing and Materials, 2011, p. 44.
[4] Compositional and Failure Analysis of Polymers, 2000, p. 399.
[5] Compositional and Failure Analysis of Polymers, 2000, p. 398, 426.

Table 1: Polypropylene Oxidative Resistance[3]

3.5.2 Polypropylene

3.5.2.1 Physical properties of polypropylene (Table 3.10)

Table 3.10 Physical properties of polypropylene

	PP Homo	PP Copo	PP Impact
Optical	Transparent to opaque	Opaque	Opaque
T_g (°C)	−5	−20	−35
H_2O Absorption	0.01	0.01	0.01
Oxidation resistance	Low, oxides readily	Low, oxides readily	Low, oxides readily
UV resistance	With stabilization high	With stabilization high	With stabilization high

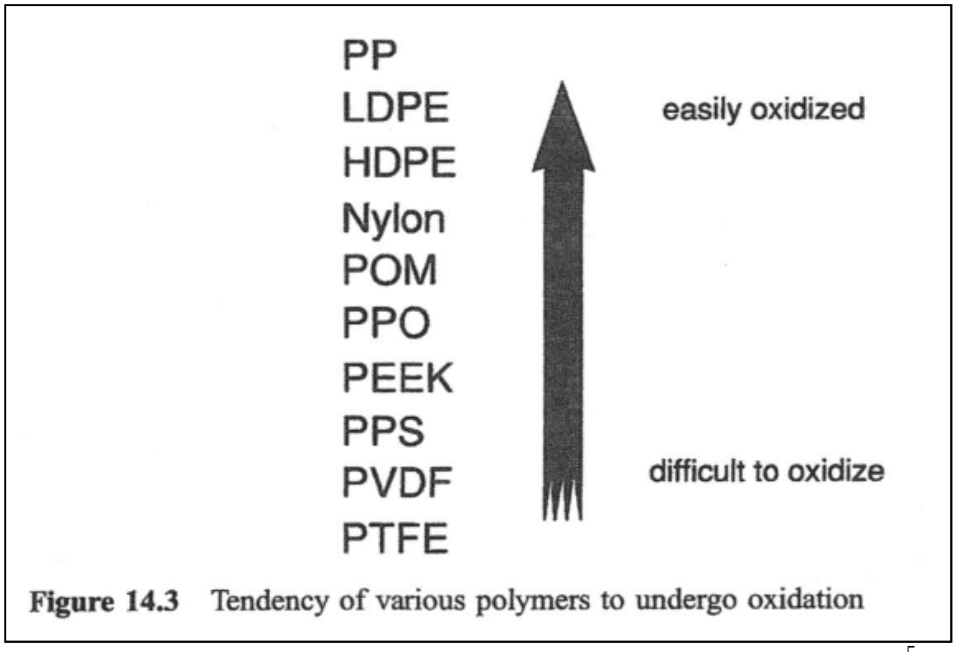


Figure 14.3 Tendency of various polymers to undergo oxidation

Figure 2. Tendency of Various Polymers to Undergo Oxidation[5]

1.3.1 Mechanism of Oxidative PP Degradation

The mechanisms of thermal and oxidative PP degradation have been investigated by the scientific extensively since the 1960s and were well known at the time that Ethicon was designing its Prolene-based pelvic mesh products. The oxidative behavior of PP described is independent of whether the polypropylene product is a medical device or a non-medical device.

The initial oxidative attack on PP will occur on the hydrogen in the tertiary carbon position; this attack is also the rate-controlling step in the polymer's oxidative process. A detailed chemical explanation of polypropylene oxidative degradation is reported in literature and is summarized below in Figure 3, emphasizing the effect of the tertiary hydrogen on the susceptibility of polypropylene to chemical oxidation. The chemical mechanism for polypropylene oxidation and degradation leads to the formation of hydroperoxide bond (COOH) formations (an intermediate) and ultimately carbonyl (C=O) bond formations. Furthermore, polypropylene will exhibit autooxidation in the presence of a reactive oxygen species (ROS).

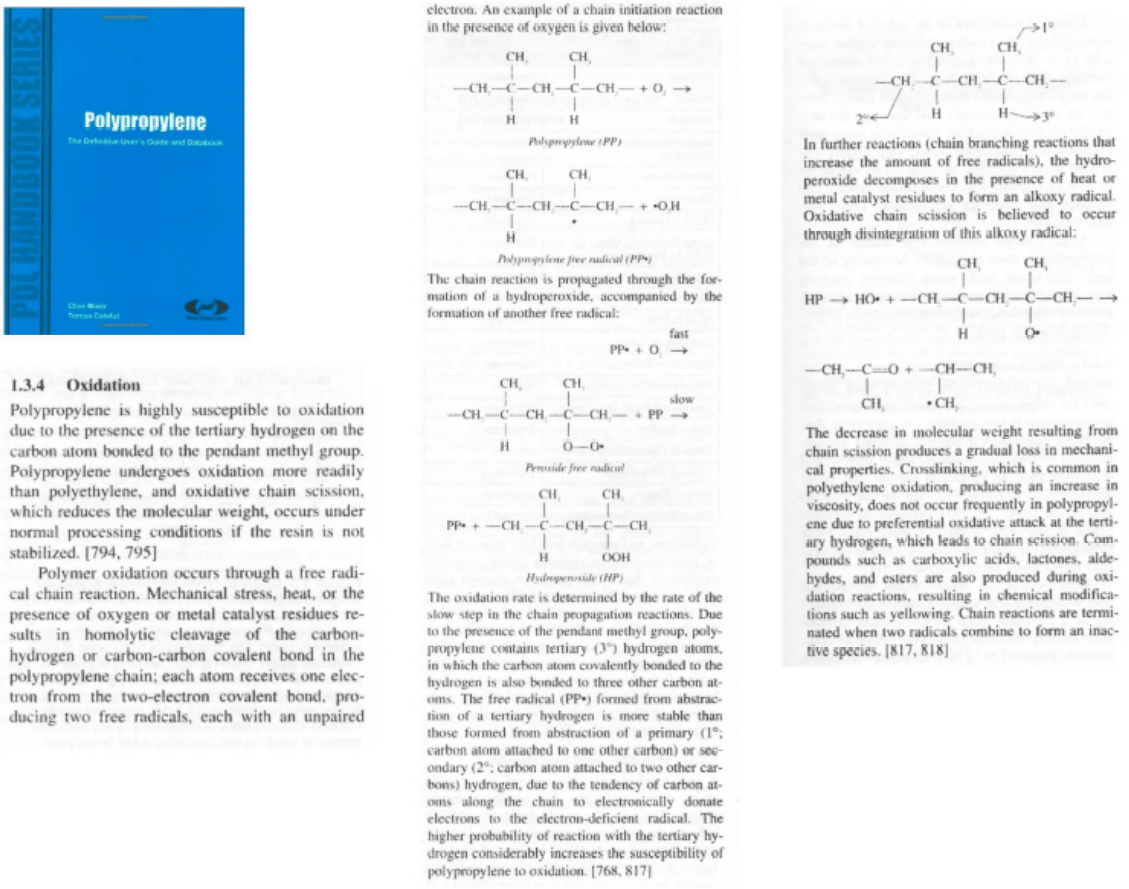


Figure 3. Oxidative Degradation of Polypropylene[6]

1.3.1 Effect of Oxidative PP Degradation

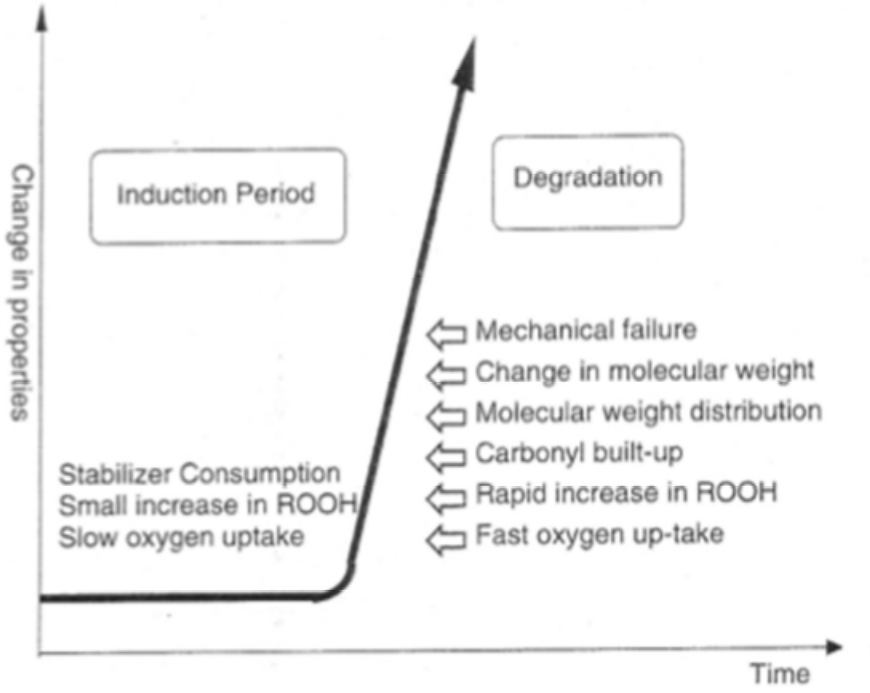
The basic mechanism of this degradation has been identified as follows:

Oxidation in PP amorphous phase => chain scission => rupture of tie chains => loss of ductility.[5]

Furthermore, this loss of ductility through oxidative degradation leads to embrittlement of the polymer, micro-crack formation, crack propagation and ultimate polypropylene polymer fracture and fragmentation.

The key features of oxidative degradation, in terms of ultimate elongation, the amount of molecular weight loss that is critical for embrittlement, and in terms of the increased carbonyl (CO) and carboxyl (OH) groups, are summarized in Figure 4.

[6] Polypropylene: The Definitive User's Guide and Databook, Maier and Calafut, 1999, p. 6-7.



Scheme 1.3 Changes in material properties during aging of polymers

Figure 4. Effect of Oxidative Degradation of Polymers[7]

In this Figure, and as discussed throughout this report, the *induction period* or *induction time* is defined as the period of time elapsed from when PP is first exposed to oxidation to the time when the polymer is transitioned to the ductile-brittle stage (also known as the embrittlement induction time, $t_{i,E}$), or the tangent on the concentration of carbonyl (or OH) groups formed on the surface of the polymer (spectrophotometric induction time, $t_{i,CO}$).

Fayolle has studied and reported this same effect on polypropylene in subcutaneous implants.[8]

Fayolle reported that at the induction time the reaction speeds up and becomes autocatalytic and with that, the concentration of carbonyl and OH groups on the surface of the PP increases dramatically. It is in this context then, that the addition of antioxidant stabilizers to polypropylene can extend the life of the resulting polymer by prolonging the time before the embrittlement stage from occurring.

Experiments on PP degradation have often been performed under accelerated conditions, such as elevated temperatures, in order to complete the experiments in a convenient period of time. However, it is important to note that the mechanism of oxidative degradation remains the same; that is, elevated temperature simply increases the rate of degradation according to the Arrhenius equation:

$$\text{rate} = A*e^{-EA/kT}$$

[7] Plastics Additives Handbook, Ch. 1 Antioxidants, Hans Zweifel, Ralph Maier and Michael Schiller, 2009, p. 6.
[8] Fayolle et al. Oxidation-induced embrittlement in polypropylene – a tensile testing study. Polym Degrad Stability 70:333-40, 2000

where A is the pre-exponential factor, E_a is the activation energy, k is the Boltzmann constant, and T is the temperature.

As previously stated, the some of the consequences of polypropylene oxidation are:

- Polymer chain scission
- Loss of polymer molecular weight
- Embrittlement
- Loss of polymer strength (cracking and ultimate mechanical failure)
- Hydroperoxide (COOH) bond increase
- Carbonyl (C=O) bond increase

1.3 Prolene Polypropylene

Ethicon uses the Prolene polypropylene for the mesh component of their transvaginal mesh products. The Prolene formulation has a polypropylene base resin purchased from Aristech and the polypropylene base resin portion comprises over 97% of the Prolene formulation. The remainder of the Prolene composition is comprised of small levels of two lubricants, two antioxidants and a colorant. Ethicon has been made aware of the specific risks inherent to using PP in an implantable medical device. One example of this is from the 2005 Material Safety Data Sheet (MSDS) that accompanied Ethicon's polypropylene; it stated:

> Section 10 (Stability and reactivity): Incompatibility: The following materials are incompatible with this product: *Strong oxidizers*, such as chlorine, *peroxides*, etc.[9] *(emphasis added)*

As previously stated, Ethicon has incorporated two antioxidants in their Prolene polypropylene, The specific antioxidants used in Prolene are Dilauralthiodipropionate (DLTDP) and Santonox R (which is a phenol)[10] First, the addition of these antioxidants in the Prolene formulation are evidence that this polypropylene is subject to oxidative degradation and must be protected from this effect. Second, the addition of these two anti-oxidants to the Prolene PP used in these pelvic meshes cannot render the material immune to oxidation. To the contrary, the correct proportion of these two anti-oxidants to maximize the time before PP embrittlement is shown in Figure 5 below.[11] Regardless of the fact that the ratios of these stabilizers are not in an optimal concentration in the Prolene material, even if it were, they would still eventually be depleted. When this occurs the PP is unprotected from oxidation. This is even more pronounced for a PP application that has a high surface area (per volume of the bulk), as it is with the mesh used in its products.

[9] ETH.MESH.05439518.
[10] Eth.Mesh.02268619
[11] Plastic Materials, John Brydson, 1999, p.261.

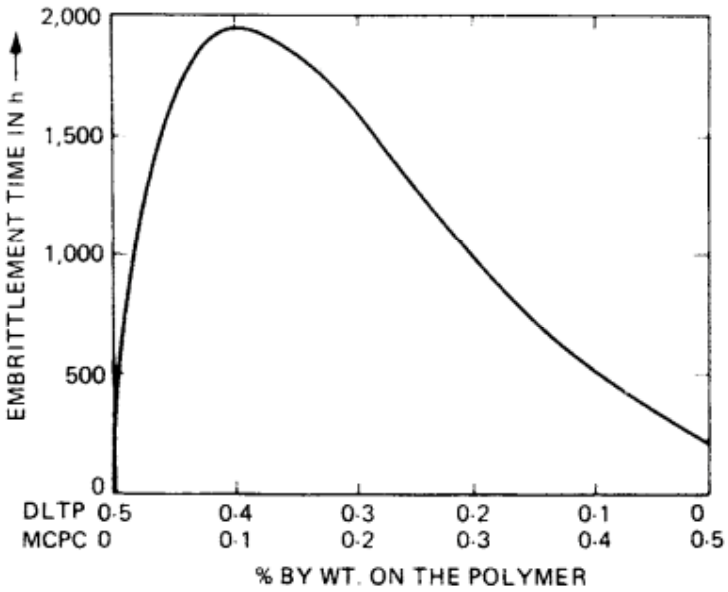


Figure 11.8. Synergistic effect of two antioxidants in polypropylene (DLTP=dilauryl thiodipropionate. MCPC–2,2′-methylenebis[6-(1-methylcyclohexyl-*p*-cresol)]. (After Leyland and Watts[8])

Figure 5. Time to Embrittlement for PP Stabilized with Phenol and/or DLTDP Antioxidants

Furthermore, Ethicon's decades-old findings of Prolene's vulnerability to oxidative changes inside the body, particularly in regards to the surface of explanted Prolene fibers that were studied internally, are supported by the chemical nature of the polymer blend, the available scientific literature[12] and an external consultant's report.[13]

In fact, Ethicon employees and consultants have reported that "decreased polypropylene content and larger pore size mesh exhibited reduction in inflammation and fibrosis"; clearly linking increased amounts of PP to increased negative effects on the body.[14] Indeed, the chemical properties of PP's reactivity, and the internal findings on explanted fibers, are not addressed in the device's design nor are they explained to the physicians who implant Prolene or those that are implanted with it. Instead, the company specifically represents that Prolene does not change and that it does not lose mechanical properties after implantation in the device's Instructions for Use ("IFU") and physician training materials.[15]

All forms of PP are susceptible to oxidation caused by the presence of a tertiary hydrogen on the polymer's chain.[16] Degradation of Prolene polypropylene is no exception. *Prolene PP is not inert.*

[12] Eth.Mesh.12831391, Eth.Mesh.12831407, Eth. Mesh. 12831405
[13] Eth.Mesh.07192412, Eth.Mesh.07192929
[14] Eth.Mesh. 04037600
[15] Eth.Mesh.00156909
[16] Industrial Polymers, 2008, p. 74.

Section 2.0 Polymer Product Failure Analysis:

2.1 Polymer Failure Analysis Applied to Medical Devices

Polymer failure analysis is a specific scientific discipline used by polymer scientists. Entire books have been written on the subject of polymer failure analysis and these sources contain numerous case studies covering a variety of polymer failures, including the failure of medical devices with one or more components made from a polymer(s).[17]

For example, Scheirs discusses the failure of a medical connector (Luer) that is used to attach intravenous lines and connect needles where the female Luer connector was found to be splitting, leaking, and cracking through polymer failure analysis.[18] In the Moalli text, the authors have addressed a shelf life prediction model for irradiated polypropylene medical devices, specifically to address catastrophic failure that have been reported during the PP shelf life period, specifically from the oxidation and embrittlement of the outer surface of the PP device. "A brittle layer is then formed and has the same effect as forming sharp notches on the sample, creating stress concentrations. Once the notch reaches a critical size, failure occurs".[19] Finally, Wright addressed the use of polypropylene for disposable medical products and clearly pointed out that PP "suffers from chain scission and severe post radiation oxidative degradation".[20]

Common themes found in these texts are:

- Failure analysis of *medical polymers* is included within the larger framework of failure analysis of any polymers. Polymer expertise is required to identify the root cause of failure.
- Numerous polypropylene based medical products have exhibited polymer failures.
- The primary root cause of failure of the polypropylene medical products cited is indeed oxidative degradation leading to chain scission, embrittlement and ultimate failure.

Specific steps should be followed when conducting polymer failure analysis. This protocol is cited in literature and one example showing the specific steps in this methodology is provided below in Figure 6.[21] The intent of polymer failure analysis is to identify the root cause of polymer failure (see section 2.4 in this report).

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[17] Plastics Failure: Analysis and Prevention, John Moalli, Editor, Plastics Design Library, 2001, 335pp.; Failure of Plastics and Rubber Products: Causes, Effects and Case Studies Involving Degradation, David Wright, 2001, Rapra Technology Limited, 371pp.; Compositional and Failure Analysis of Polymers: A Practical Approach, John Scheirs, 2000, John Wiley & Sons, 740pp.

[18] Compositional and Failure Analysis of Polymers: A Practical Approach, John Scheirs, 2000, p. 352.

[19] Plastics Failure: Analysis and Prevention, John Moalli, Editor, Shelf Life Failure Prediction for Irradiated Polypropylene Medical Devices, 2001, p. 201-207.

[20] Failure of Plastics and Rubber Products: Causes, Effects and Case Studies Involving Degradation, David Wright, 2001, p. 148.

[21] Characterization of Plastics in Failure Analysis, ASM Handbook, Vol. 11: Failure Analysis and Prevention, 2002, p. 437-459; Failure of Plastic Press Release Buttons in Automobile Seat Belts, 2005, R. F. Dunn, R. H. McSwain, T. Mills and B. Malone, *Engineering Failure Analysis*, 12, 81-98.

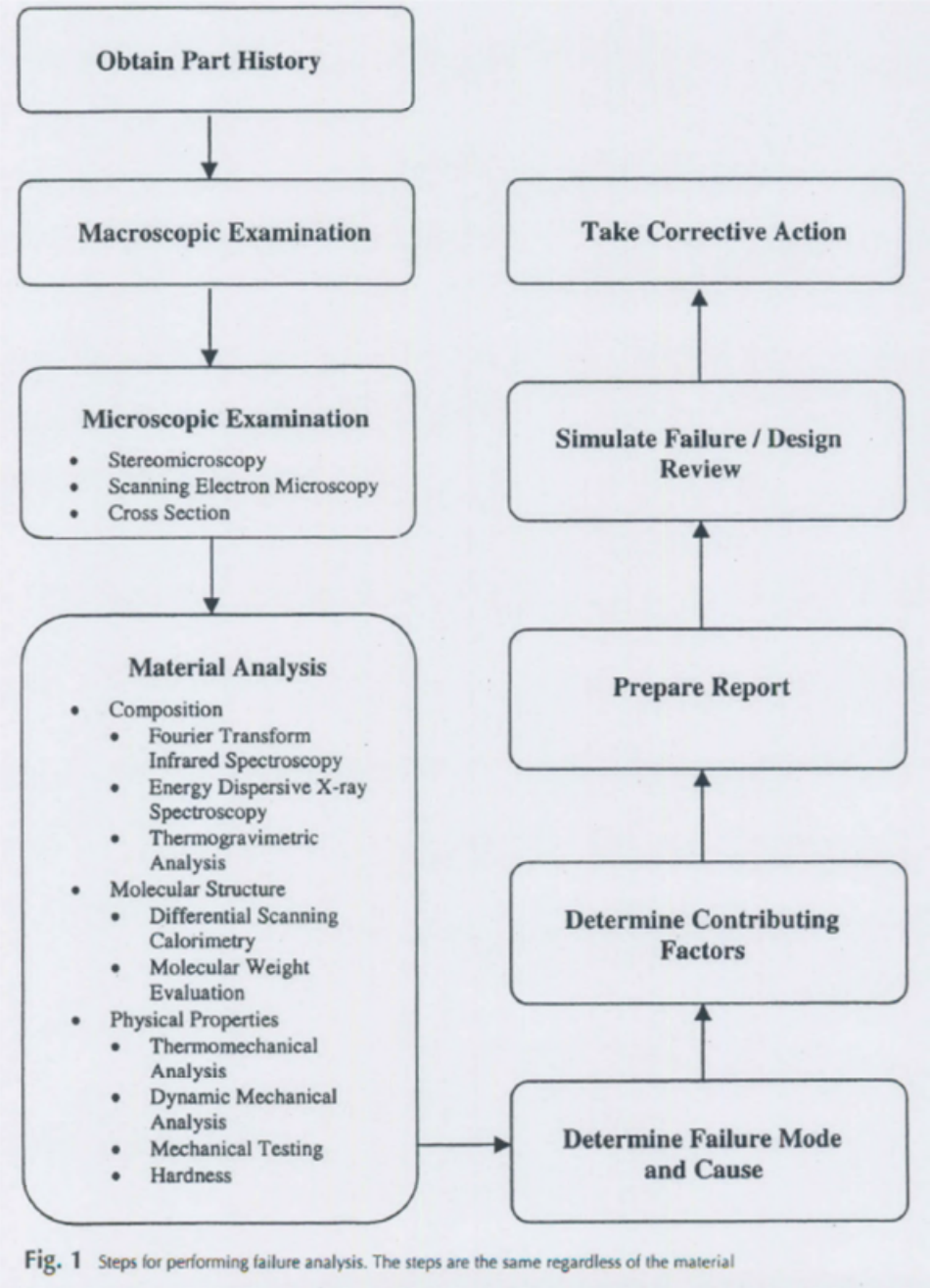

Figure 6. Polymer Failure Analysis Protocol

2.2 Microscopic Examination (Fractography) of Polymer Failures and Its Significance

Microscopic examination (stereo microscopy, scanning electron microscopy, etc.) of polymer failures is one of several critical steps in polymer failure analysis protocol. It is the third step shown previously in the failure analysis protocol provided in Figure 6. Again, this is specific field of polymer science called "fractography" and it focuses on microscopic features of polymer failures, generally at the fracture

surface. Entire books[22] are devoted to this subject and the American Society of Materials Handbook in Vol. 11 Failure Analysis and Prevention in their chapter on Fracture of Plastics has provided an overview article on this specific subject.[23] Microscopic examination, or fractography, is conducted on a failed polymer component regardless of what application the product was designed for. It does not matter if the polymer product was used in the body or outside the body; the microscopic examination technique and evaluation is the same.

Fractography is used to identify and analyze cracks. Specifically, polymers that crack and are under stress will exhibit crack propagation (crack growth), until ultimate polymer failure (fracture) occurs. Other polymer property changes, such as embrittlement, can occur prior to and contribute to ultimate failure. Microscopic examination of polymers is one of the techniques used to aid in the identification the root cause of polymer failure (see section 2.4).

2.3 Chemical and Thermal Analysis of Polymer Failures and Their Significance

Material analysis (chemical and thermal property analysis such as infrared spectroscopy, differential scanning calorimetry, etc.) of failed polymer components is one of several critical steps in polymer failure analysis protocol. It is the fourth step shown previously in the failure analysis protocol provided in Figure 6. This is specific field of polymer science called "fractography" and it focuses on features of polymer failures, generally at the fracture surface. Entire books[24] are devoted to this subject and the American Society of Materials Handbook in Vol. 11 Failure Analysis and Prevention in their chapter on Characterization of Plastics in Failure Analysis have provided an overview article of these techniques and how they can be used applied to polymer failure analysis.[25] Numerous chemical and thermal analysis techniques can be conducted, as required, on a failed polymer component regardless of what application the product was designed for. It does not matter if the polymer product was used in the body or outside the body; the material analysis is the same. Material analysis of polymers employs techniques that are used to aid in the identification the root cause of polymer failure (see section 2.4).

2.4 Identification of the Root Cause of Failure

Understanding how and why a polymer-based product failed is a crucial part of maintaining its safety and efficacy. This makes the need to understand the root cause of polymer failure paramount to maintaining a robust design.

> "The ultimate objective of a failure analysis is to ascertain the mode and cause of the failure, regardless of the material from which the part was fabricated…Reaching the objectives of the plastic failure analysis, namely, the determination of the mode and cause of failure, or expressed alternatively, evaluating how the part failed, requires a scientific approach and a broad knowledge of polymeric materials." "In many cases, a single cause cannot be identified, because multiple integrated factors may have contributed to the failure. All of the factors that affect the performance of a plastic component can be classified into one of four categories: material, design, processing, and service conditions.

[22] Polymer Microscopy, Second Edition, 1996, Linda C. Sawyer and David T. Grubb, 399pp.; An Atlas of Polymer Damage, Engel, Klingele, Ehrenstein, and Schaper, 1981, 256pp.; Fractography: Observing, Measuring and interpreting Fracture Surface Topography, Derek Hull, 1999, 366pp.
[23] Fracture of Plastics, ASM Handbook, Vol. 11: Failure analysis and Prevention, 2002, p. 650-661.
[24] Polymer Microscopy, Second Edition, 1996, Linda C. Sawyer and David T. Grubb, 399pp.; An Atlas of Polymer Damage, Engel, Klingele, Ehrenstein, and Schaper, 1981, 256pp.; Fractography: Observing, Measuring and interpreting Fracture Surface Topography, Derek Hull, 1999, 366pp.
[25] Fracture of Plastics, ASM Handbook, Vol. 11: Failure analysis and Prevention, 2002, p. 650-661.

> These factors do not act independently on the component but instead act in concert to determine the performance properties of the plastic component."[26]

This approach is standard for studying all types of polymer failures and it is represented in Figure 7 below.[27] It does not matter if the polymer product was used in the body or outside the body; these factors that affect the performance of a plastic component are the same.

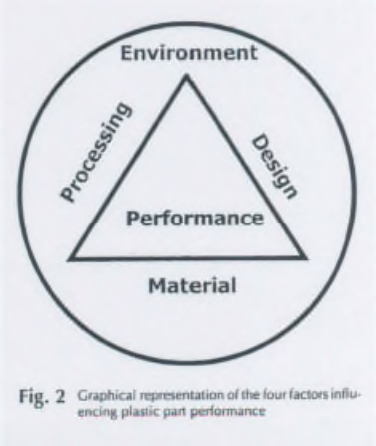

Figure 7. The Four Factors Influencing Plastic Part Performance

3.0 Ethicon's Internal Polymer Failure Analysis Studies

3.1 Ethicon Internal Studies Showed Oxidative Degradation of their Prolene Polypropylene

Ethicon observed evidence of PP oxidation and degradation in their own internal studies starting in the 1980's. At many points in time since first studying explanted material, Ethicon scientists have concluded that Prolene is vulnerable to oxidative changes inside the body—particularly in regards to the surface of the material.

- In 1982, Dr. Anthony Lunn reported in an internal Ethicon study that surface cracks were found on Prolene sutures explanted from vascular implants and ophthalmic implants.[28] Specifically, this report evaluated the surface crack depth on these implants. Surface cracks were found on sutures from both the vascular and ophthalmic implants. Dr. Lunn pointed out that "crack depth does not vary systematically with implantation time; it does vary significantly from point to pint along the fiber length".
- In 1983, Ms. Barbara Matlaga and Drs. W. D. Sheffield and A. W. Fetter published in an internal Ethicon study on Prolene (polypropylene) microcracks.[29] In this report, the authors noted that the "latest "human retrieval" specimens of Prolene suture showed surface microcracking. They further reported that they could show slides of these cracks "at the next Prolene Microcrack Committee" meeting. Furthermore, they concluded "surface cracking was noted on the Prolene sample from both explants. Why the cracking occurred or it this condition contributed to the loss of breaking strength (54%) could not be determined from this type of examination".
- In 1984, Dr. Peter Moy reported in an internal Ethicon study that microcracking of explanted

[26] Characterization of Plastics in Failure Analysis, ASM Handbook, Vol. 11: Failure Analysis and Prevention, 2002, p. 437.
[27] Id. P. 438.
[28] ETH.MESH.12831405, ETH.MESH.15406978
[29] ETH.MESH.15955438

Prolene sutures from vascular grafts was observed[30]. Dr. Moy points out "a great body of literature exists regarding oxidative degradation of polypropylene in general as well as selective studies on the photo- and thermal-oxidation of polypropylene monofilaments". He recommended further studies to examine "known oxidized Prolene samples".

- In 1985, a new Ethicon internal study was initiated where "twenty-four Beagle dogs were implanted in November 1985 with sutures made from four different polymers.[31] Each polymer suture type was implanted in six different locations (sites) in each dog. One of the suture polymer materials included in this study was Prolene PP. The study was referred to in Ethicon internal memos as the "*In Vivo* suture study".
- In 1987, Daniel F. Burkley, a Principal Scientist at Ethicon, examined Prolene sutures that were "carefully removed from human vascular graft explants".[32] Sutures were examined that had been in the body for 2 years and 8 years, respectively. Mr. Burkley conducted chemical analysis using infrared spectroscopy and also performed microscopic examination. Sutures that were in the body for eight years "were severely cracked specimens". Furthermore, Mr. Burkley stated that the surface of the sutures appears to be degraded polypropylene. He further concludes that he observes no protein in the FTIR (Fourier Transform Infrared Spectroscopy) spectra of the explanted sutures and that the FTIR spectra show that scraped surface material is consistent with polypropylene that has been "degraded in an oxidative fashion". He also observed changes in the DLTDP concentration, one of the antioxidants in Prolene, in the explanted Prolene sutures. He specifically reports that there is "no DLTDP observed in the surface scraped (cracked regions)" and that "the observed DLTDP decreases with implant time". Finally, Mr. Burkley also reported that the surface scrapings from the sutures that had been in the body for eight years (severely cracked) showed a melting point between 147-156^{o}C and that "this is the melting range previously observed for oxidatively degraded polypropylene."
- In 1987, a meeting was held to discuss the study previously cited above from that year.[33] Dr. Satya Garg published meeting minutes. In the meeting minutes, Dr. Garg reported:
  - Scanning electron microscopy showed that "explants with 7-9 years of residence time showed cracking"
  - Mr. Burkley examined the 2 and 8 year samples using IR spectroscopy. IR analysis showed "no proteinaceous material could be detected on either of the samples."
  - "The surface of the 8 year sample could be easily scraped off. The material scraped from the cracked surface regions of the 8 year sample showed IR bands indicative of oxidation. The same material exhibited a melting range of 147-156^{o}C which had been earlier assigned to oxidatively degraded polypropylene".
  - "Mr Burkley is planning to look at the remaining dry explants by IR. He will also try to see the relationship between the amount of stabilizers added to the polymer and degradation and cracking."
- In 1990, Elke Lindemann wrote an internal Ethicon five year report on the "*In Vivo* suture study". Specifically, five of the dogs were euthanized and the suture implants were removed for scanning electron microscopy examination. She concluded "out of seven Prolene explants, two revealed cracking". She further concluded that "after 5 years in vivo the PVDF suture was the only explanted material from five dogs that did not show any surface damage due to degradation."[34] This is consistent with the potential for oxidative degradation previously shown

[30] ETH.MESH.15958453
[31] ETH.MESH.11336474
[32] ETH.MESH.12831391
[33] ETH.MESH.12831407, ETH.MESH.15406846-15406999, ETH.MESH.15406978, ETH.MESH.15955438-15955473, ETH.MESH.15958336-15958469, ETH.MESH.15958470-15958477, ETH.MESH.15958336-15958469, ETH.MESH.
[34] ETH.MESH.11336474

in Figure 2 of this report.

- In 1990, Elke Lindemann, Eugene Muse, and Daniel Burkley, wrote an internal Ethicon seven year report on the "*In Vivo* suture study".[35] Specifically, four of the dogs were euthanized and the suture implants were removed for scanning electron microscopy examination. These Ethicon scientists concluded in this report that "the 7 year *in vivo* results generally substantiated the five year findings". The group further concluded that "degradation in Prolene is still increasing and PVDF, even though a few cracks were found, is still by far the most surface resistant in-house made suture in terms of cracking". Again, this is consistent with the potential for oxidative degradation previously shown in Figure 2 of this report.
- In 1999, Robert Rousseau, an Ethicon Staff Engineer in Suture Technologies, became the Project Leader for a "Prolene Mesh Improvement" project. Even at that time there was no consideration to change the material of construction from Prolene PP.[36]

3.2 Ethicon Failed to Investigate the Root Cause of Prolene Mesh Failures

Ethicon observed the oxidative degradation of their Prolene polypropylene as early as the 1980's. One example of this is from the 2005 Material Safety Data Sheet (MSDS) that accompanied Ethicon's polypropylene; it stated:

> Section 10 (Stability and reactivity): Incompatibility: The following materials are incompatible with this product: *Strong oxidizers*, such as chlorine, *peroxides*, etc.[37] *(emphasis added)*

As explained previously, as long as there is a source of oxygen, all polypropylene will be susceptible to oxidative changes, whether the polymer is implanted in a human being or if it is being stored at room temperature. The MSDS warning and the risks inherent to using a polypropylene-based mesh in the human body have not been addressed, which is to the detriment of all of those who have been implanted with this mesh.

This potential for oxidative degradation of Prolene polypropylene mesh was again reiterated to Ethicon in June 2011 through a technical review "Investigating Mesh Erosion in Pelvic Floor Repair."[38] This technical review was performed by PA Consulting Group at the request of Ethicon.

Furthermore, Ethicon's internal Prolene explant studies that employed industry-standard failure analyses and other evidence of oxidation should have led to the need for performing more testing on Prolene's reactivity before implanting their pelvic mesh into women.

At no time that I am aware has the potential failure mode of "oxidative degradation" of the Prolene-based mesh component of Ethicon's pelvic mesh products ever been considered and documented as a potential failure mode. As an illustration of the root cause of failure and the defective nature of these meshes, a summarized diagram is given below in Figure 8.

[35] ETH.MESH.09888187
[36] ETH.MESH.02608450
[37] ETH.MESH.05439518
[38] ETH.MESH.03750936-03750937

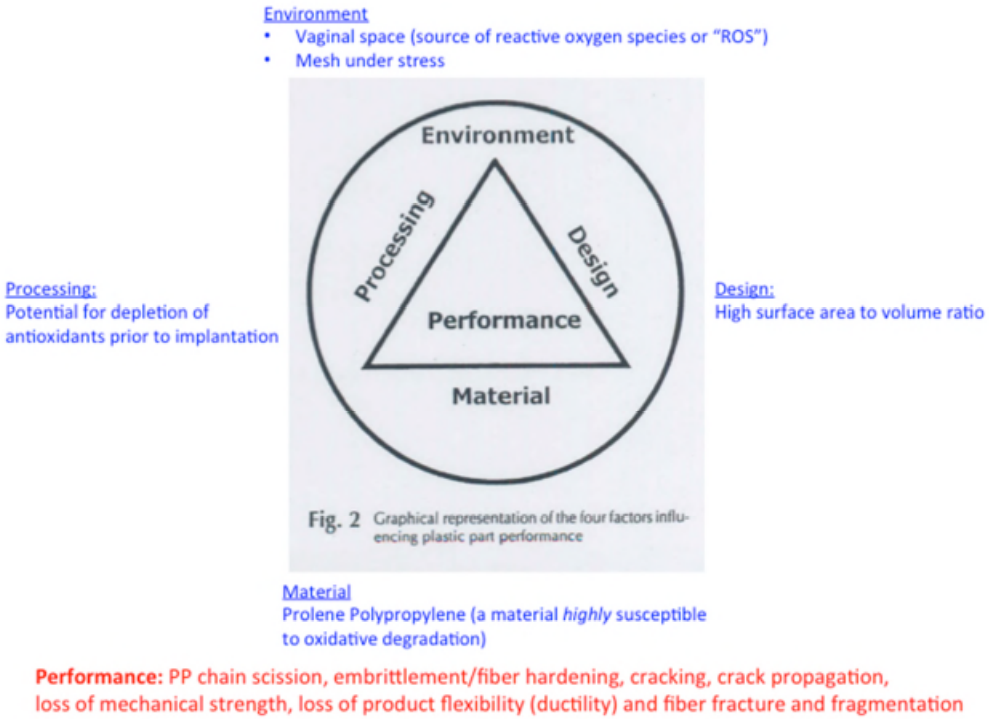

Figure 8. The Four Factors Influencing Plastic Part Performance Applied to Prolene-Based Mesh

3.3 Ethicon's Pelvic Mesh Products that Contain a Prolene-Based PP mesh are Defective

The Ethicon's pelvic mesh products are of a defective design since they contain Prolene-based meshes, a material that is highly susceptible to oxidation. All mesh components in every pelvic mesh device have this flaw. The potential for oxidation of Prolene polypropylene is common knowledge in the scientific community and the internal studies indicated that this was indeed occurring inside the body and that it resulted in polypropylene fiber embrittlement, cracking and a loss of fiber strength. Failure to account for this potential for polymer failure has resulted in the implantation of defective devices in patients. Identification of this defect in the mesh component of these products was both foreseeable and avoidable.

V. SUMMARY OF PRODUCT DESIGN OPINIONS

1) As part of its device design process, Ethicon performs risk management activities to ensure that any risks associated with its products are either designed out of the product or that those risks are mitigated as much as possible. The Standard Operating Procedure ("SOP") at Ethicon is to employ a Failure Modes and Effects Analysis to assess and mitigate these potential risks before any product is launched and while it is on the market. This SOP was not followed properly with respect to the Prosima, Prolift and Prolift+M devices.

2) Ethicon did not prior to product launch, or has not to date, considered oxidative degradation as a potential failure mode for their Prolene PP Gynemesh products. This is in direct contradiction of polymer literature on polypropylene oxidation, Ethicon's own internal studies, vendor MSDS sheets and external consultant studies.

3) Ethicon has not investigated the oxidative degradation of its Prolene polypropylene in their Prosima, Prolift and Prolift+M product's risk analysis. Had this potential failure mode been considered, it would have led to an evaluation of the risk of injury associated with this type of failure and would also have led to testing that assessed both the frequency and severity of it. Because of this, known risks of the Prosima, Prolift and Prolift+M products are not being mitigated to those who implant or are implanted with any of these products.

4) The risk analysis associated with oxidative degradation of the Prolene-based component of the Prosima, Prolift and Prolift+M devices was not adequately measured or assessed in terms of possible failure modes, frequency of occurrence, in terms of changes to mechanical properties, and in terms of the potential for harm caused prior to when this product was placed on the market; these deficiencies are lacking to this day.

5) The design of the Prosima, Prolift and Prolift+M devices was faulty in that Ethicon knew of a specific design defect before it ever launched these products: the high susceptibility of its Prolene PP to oxidatively degrade. Yet the design of the Prosima, Prolift and Prolift+M devices did not eliminate or mitigate the resulting risk of harm to the implantee.

6) The Prolene polypropylene mesh used in the Prosima, Prolift and Prolift+M devices is a defective design. Identification of the oxidative degradation design defect in these products was both foreseeable and avoidable.

VI. PROSIMA, PROLIFT AND PROLIFT+M PRODUCT DESIGN OPINIONS

1.0 Product Design

1.1 Phases of Product Design[39]

Different companies may have various descriptions for each phase of the product design and development process, but Robert Cooper's The Stage-Gate - Product-Development Process (SGPDP) captures the essence of this process and provides a roadmap to transform ideas into products that meet a consumer need. The typical phases may include:

(1) *Concept.* This phase includes idea generation, the development of a superior product concept, an identification of customer needs, market assessment, and the development of a risk assessment. The goal is to define the product and build the business model.

(2) *Feasibility.* This phase includes validating the superior product concept, building a business case, updating the market assessment, examining the health-safety concerns. Deliverables include product performance, a product prototype, and a case for the economic value of the product in the face of competition.

(3) *Design.* The objective during this phase is to fully develop the product and finalize the design. The deliverables include the product specification, a feasibility of the manufacturing, updating of market assessment, competitive analysis, and health and safety. The health and safety aspect are evaluated through an overall *Risk Management Plan.* A key component of the Risk Management Plan is an assessment of potential risks associated with product failures. This risk is addressed using a risk estimation tool such as Hazard/Risk analysis, *Failure Modes and Effects Analysis (FMEA),* or Fault Tree Analysis (FTA).

(4) *Verification.* This phase involves proving that the design meets all the requirements of the product. Testing at various levels of the design is conducted along a rigorous outline to assure the product meets the design requirements. All results are documented.

(5) *Manufacturing.* The goal is to develop a process to manufacture the product that meets the product specifications set in the design phase. A quality-assurance plan should be implemented and tested. The product is sampled and tested to assure it meets the design specifications.

(6) *Product Field Activity.* This phase involves monitoring and validating product performance and function in the field, assessing the product's success in achieving the intent of the design, analyzing field data, analyzing success and failure data, and documenting everything. This includes establishing and maintaining a functioning Quality System that obtains, tracks, and trends information regarding the product's function in the field (in this case after implantation). This information is then analyzed and fed back into the product's FMEA so that a decision can made regarding whether changes are warranted to the FMEA in design, warnings or if other remediating actions are required.

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[39] Product and Process Design Principles: Synthesis, Analysis and Evaluation, 3rd Edition, Seider, Seader, Lewin and Widalgo, 2009, 728pp.; Reliable Design of Medical Devices, Third Edition, Richard C. Fries, 2013, 471pp.

1.2 Risk Management Plan and Failure Mode and Effects Analysis

1.2.1 The Risk Management Plan

The Risk Management Plan outlines the specific risk assessment and risk minimization activities (if needed) associated with a product. The primary purpose of a Risk Management Plan is to proactively and systematically describe a set of specific safety monitoring and evaluation activities designed to identify, characterize, and minimize and/or prevent risks that may occur with the use of a particular product. After a product receives approval and is made available to patients, the Risk Management Plan continues to be updated as additional information becomes available that impacts the safety profile or benefit/risk balance of the product.

Specific instructions for risk management of medical devices can be found in ISO 14971 Medical Devices – Application of risk management to medical devices.[40] Ethicon uses the recommendations in ISO 14971 as guidance for its risk analysis for medical devices, including the use of the failure mode and effects analysis, [41] but the use of the FMEA is also mandated by internal SOP to provide a "methodology for evaluating and analyzing risks resulting from potential failure modes, with the objective of eliminating or minimizing these risks to an acceptable level with the current state of technology."[42]

Basic Elements of a Risk Management Plan:

• Identifies the important established or potential risks on the basis of non-clinical, clinical and post-marketing data

• Outlines how the risks will be monitored for further evaluation (e.g. by conducting additional studies, monitoring of existing databases)

• Specifies how the risk will be mitigated through a risk minimization plan. This plan describes a set of activities for minimizing the identified or potential risks of a product in order to optimize the benefit/risk balance.

Ethicon has stated that the risk analysis part of their Risk Management Plan to was intended for the:

- "identification of known or foreseeable hazards (such as oxidative degradation of Prolene polypropylene)
- identification of risks for hazardous situations" [43]

Oxidative degradation of the Prolene polypropylene was a foreseeable hazard based solely on the oxidative degradation properties of polypropylene that have been well documented outside the body for several decades.

Under this Risk Management Plan, oxidative degradation of Prolene polypropylene was a foreseeable hazard based solely on the oxidative degradation properties of polypropylene that have been well

[40] ISO 14971 Medical Devices – Application of risk management to medical devices, Second edition, 2007-10-01.
[41] ETH.MESH.22007225
[42] ETH.MESH.03742864
[43] ETH.MESH.22007254

documented outside the body for several decades. In addition, and as discussed later and in more detail in this report, Ethicon performed several internal studies that concluded Prolene polypropylene oxidized and degraded while inside the body—many years before the Prosima device was first marketed. This means that the foreseeable and known hazards associated with using Prolene polypropylene in the Prosima mesh were apparent before it was ever used for its intended purpose—making the design of the Prosima defective according to standards set forth in Ethicon's Risk Management Plan.

1.2.2 Failure Mode and Effects Analysis

This type of analysis, Failure Modes and Effects Analysis ("FMEA"), began in the 1940s by the U.S. military and was further developed by the aerospace and automotive industries. NASA was one of the first organizations that used the FMEA on a regular basis. It was instituted in NASA after space shuttle challenger incident in 1986.

An FMEA is a step-by-step systematic safety analysis that is conducted by a team comprised of members having diverse and overlapping expertise for identifying all possible potential mode of failures in a design. "Failure modes" means the ways, or modes, in which something might fail. Failures are any errors or defects, especially ones that affect the customer, and can be potential or actual. "Effects analysis" refers to studying the consequences of those failures.

The FMEA also encompasses the identification of the potential cause of these failure modes, an estimate of their severity, their potential occurrence rate (frequency), as well as the potential for these failures to be detected. For an FMEA to work, all of these must be identified to ensure that the product's design is as robust as possible. Thereafter, the product's design process requires that the manufacturer attempt to mitigate the risks identified in the FMEA prior to marketing the product. This can occur through re-design, by way of instructions, by warning about the hazards, by training the product's users, or by any other means necessary.

As part of the FMEA process, and in order to design the product to be as robust as possible, it is crucial that manufacturers obtain inputs from many types of engineering designers, as well as those intended to use the product and other related professionals. Specifically, ISO 14971 provides the following guidelines concerning the qualification of the personnel involved in the FMEA generation:

> "It is most important to get people with the expertise necessary to perform risk management tasks. The risk management process requires people with expertise in areas such as:
>
> - how the medical device is constructed;
> - how the medical device works;
> - how the medical device is produced;
> - how the medical device is actually used;
> - how to apply the risk management process.
>
> In general, this will require several representatives from various functions or disciplines, each contributing their specialist knowledge. The balance and relation between individuals performing risk management tasks should be considered."[44]

[44] ISO 14971 Medical Devices – Application of risk management to medical devices, Second edition, 2007-10-01.

As an example, a specialized *medical doctor* would have more expertise on:
- how the medical device works;
- how the medical device is actually used

and a specialized *chemical engineer/polymer engineer* would have more expertise on:
- how the medical device is constructed (e.g. polymer materials and properties);
- how the medical device is produced (manufacture of base PP polymer and Prolene fibers used in the Gynemesh);

and a specialized safety professional would have expertise on:

- how to apply the risk management process

As an example, Ethicon included the following personnel expertise as part of their design FMEA team for their Prolift device:[45]

- Gynecare R&D Project Leader
- Design Quality Engineer
- Packaging R&D Engineer
- Medical Director
- Design Quality Engineer
- Operation Integration Project Manager
- Medical Affairs Manager
- Equipment Engineer
- Process Engineer
- Process Engineer
- Quality Engineer

My expertise overlaps with Quality Engineers with expertise in FMEA's, an R&D Project Leader and Process Engineer. Several of Ethicon's design FMEA analysis did not have this depth of expertise on the safety analysis team.[46] It is unknown to me at this time if any of these individuals had sufficient polymer engineering background to understand the properties of polypropylene.

While there is often overlap between these medical, polymer and safety expertise, it is imperative that all of these skills are an integral part of the FMEA team that is conducting the risk analysis. The ISO 14971 standard clearly recognizes that the appropriate analysis of any potential failures requires a multi-discipline team and certainly not just medical doctors who have little, to no, polymer product training and polymer chemistry and property assessment.

The FMEA is not the end of a manufacturer's obligation to ensure that its products work as intended and are safe for their use. Instead, the FMEA is considered a living document that must be modified to take into account any additional risks or failure modes that are identified once a product has been placed on the market. To do this, product manufacturers create cyclical and redundant quality systems that monitor their products and feed information about any potential or additional risks that are encountered during their manufacture and use. After any information about a product's failure is gathered, it is then analyzed by the manufacturer who identifies the root cause of the product's failure. If and when an

[45] ETH.MESH.12288401, ETH.MESH.00876900
[46] Id.

additional risk is identified—that risk must be added to the original FMEA. This information regarding potential additional failure modes includes all information that can be learned from returned products (breakage, loss of components) as well as complaints of product failure and adverse events.

This evaluation and analysis process then repeats itself for every complaint or product failure for the entire life of the product. If properly employed, the FMEA is a powerful tool that will create and maintain a robust product design and it will help ensure that the product is on the market is safe and effective, that known and knowable risks will be identified, and warned about or mitigated.

It is crucial that the manufacturer obtain input from many types of professionals when developing the FMEA. A *Design FMEA* (D-FMEA)[47] is conducted during the design phase of product development and a *Process FMEA* (P-FMEA)[48] is conducted on the manufacturing process for a new product. An *Application FMEA*[49] is used to assess the specific steps associated with the use of a new product.

The Design FMEA is the critical safety assessment that is conducted by a manufacturer on a new product and this assessment evaluates each of the individual components that make up a product system. This includes such components as a trocar, a mesh(es), sheath covers, packaging, etc. when evaluating a transvaginal medical device used for SUI treatment. A manufacturer will systematically evaluate the safety of each component of the device along with any interactions between components, when conducting the Design FMEA. *The Design FMEA is the specific safety assessment that should include the potential failure mode of oxidative degradation for the mesh component of these mesh products.*

An FMEA requires the identification of all potential failure modes for a particular product. For each potential failure mode an estimate is made of its severity (S), of its occurrence rate (O) and its ability to be detected (D). Each of these rankings (S, O, & D) is typically on a scale of 1-10.

Examples of severity ranking criteria found in *Guidelines for Failure Mode & Effects Analysis for Medical Devices* and in ISO 14971 and these examples are provided in Tables 9 and 10, respectively.

[47] *Guidelines for Failure Mode & Effects Analysis for Medical Devices*, Chapter 11.
[48] *Id.* at Chapter 12
[49] *Id.* at Chapter 13

Table 9. ***Guidelines for Failure Mode & Effects Analysis for Medical Devices***

Severity Ranking – Example 1

Table 11-1: Suggested Severity Ranking for D-FMEA (1-10 qualitative scale)

Effect	Rank	Criteria
None	1	No effect.
Very Slight	2	Negligible effect on product performance. User not affected.
Slight	3	Slight effect on product performance. Non-vital faults will be noticed most of the time.
Minor	4	Minor effect on product performance. User slightly dissatisfied.
Moderate	5	Reduced performance with gradual performance degradation. User dissatisfied.
Severe	6	Product operable and safe but performance degraded. User dissatisfied.
High Severity	7	Product performance severely affected. User very dissatisfied.
Very High Severity	8	Product inoperable but safe. User very dissatisfied.
Extreme Severity	9	Product failure resulting in hazardous effects highly probable. Compliance with government regulations in jeopardy.
Maximum Severity	10	Product failure resulting in hazardous effects almost certain. Non-compliance with government regulations.

50

Table 10. ***Guidelines for Failure Mode & Effects Analysis for Medical Devices***

Severity Ranking – Example 2

Table D.3 — Example of five qualitative severity levels

Common terms	Possible description
Catastrophic	Results in patient death
Critical	Results in permanent impairment or life-threatening injury
Serious	Results in injury or impairment requiring professional medical intervention
Minor	Results in temporary injury or impairment not requiring professional medical intervention
Negligible	Inconvenience or temporary discomfort

51

Likewise, examples of occurrence and detection ranking criteria found in *Guidelines for Failure Mode & Effects Analysis for Medical Devices* are shown in respectively in Tables 11 and 12 below.

[50] *Guidelines for Failure Mode & Effects Analysis for Medical Devices*, Chapter 11.
[51] ISO 14971 Medical Devices – Application of risk management to medical devices, Second edition, 2007-10-01.

Table 11. ***Guidelines for Failure Mode & Effects Analysis for Medical Devices***

Occurrence Ranking

Table 11-2: Suggested Occurrence Ranking for D-FMEA (1-10 qualitative scale)

Occurrence	Rank	Criteria
Extremely Unlikely	1	Failure highly unlikely.
Remote Likelihood	2	Rare number of failures likely.
Very Low Likelihood	3	Very few failures likely.
Low Likelihood	4	Few failures likely.
Moderately Low Likelihood	5	Occasional failures likely.
Medium Likelihood	6	Medium number of failures likely.
Moderately High Likelihood	7	Moderately high number of failures likely.
High Likelihood	8	High number of failures likely.
Very High Likelihood	9	Very high number of failures likely.
Extremely Likely	10	Failure almost certain.

Table 12. ***Guidelines for Failure Mode & Effects Analysis for Medical Devices***

Detection Ranking

Table 11-3: Suggested Detection Ranking for D-FMEA (1-10 qualitative scale)

Detection	Rank	Criteria
Extremely Likely	1	Can be corrected prior to engineering prototype.
Very High Likelihood	2	Can be detected and corrected prior to engineering design release.
High Likelihood	3	Has high effectiveness.
Moderately High Likelihood	4	Has moderately high effectiveness.
Medium Likelihood	5	Has medium effectiveness.
Moderately Low Likelihood	6	Has moderately low effectiveness.
Low Likelihood	7	Has low effectiveness.
Very Low Likelihood	8	Has lowest effectiveness in each applicable category.
Remote Likelihood	9	Is unproven, unreliable or unknown.
Extremely Unlikely	10	No design technique available or known, and/or none is planned.

A Risk Priority Number (RPN) is assigned by multiplying the rankings for severity, occurrence and detection (RPN = Severity x Occurrence x Detection); therefore, an RPN is between 1-1000. The following are some key criteria when using an FMEA safety analysis:

• "An RPN greater than or equal to 100 indicates that there might be a high risk item."[52]

• "When the severity is very high (8-10), special attention must be given to ensure that the risk is addressed through existing design controls or corrective/preventive actions, regardless of the RPN."[53]

• "The severity can only be reduced through a change in the design. If such a design is attainable, the failure can possibly be eliminated."[54]

• "In the absence of any data on the probability of occurrence of harm, it is not possible to reach any risk estimate, and it is usually necessary to evaluate the risk on the basis of the nature of the harm alone. If it can be concluded that the hazard is of little practical consequence, the risk can be judged to be acceptable and no risk control measures are necessary. However, for significant hazards, that is, hazards which could inflict harm of high severity such as those noted above, no level of exposure can be identified that corresponds to a risk so low that there is no need to bother about it. In such cases, the risk estimate should be made on the basis of a reasonable worst-case estimate of probability."[55]

Although all three (severity, occurrence and detection) are important, special attention should be paid to severity. The FMEA also documents current knowledge and actions about the risks of failures, for use in continuous improvement. It is used during design to prevent failures and it is later used for control, before and during ongoing operation of the process. Ideally, FMEA begins during the earliest conceptual stages of design and continues throughout the life of the product or service.

Risk control to design for inherent safety of a medical device can be achieved by: [56]

- eliminating a particular hazard,
- reducing the probability of occurrence of the harm

or

- reducing the severity of the harm.

The proper way for Ethicon to completely eliminate the hazard of oxidative degradation of the Prolene PP mesh component of its pelvic mesh products is to use a suitable polymer, other than Prolene-polypropylene, that is not highly susceptible to oxidative degradation.

1.2.3 Ethicon Safety Analysis and Design FMEA for Its Prosima, Prolift and Prolift+M POP Products Containing Prolene PP Mesh

Ethicon uses Prolene PP in the form of knitted monofilaments as part of the mesh component of its Prosima, Prolift and Prolift+M products. Ethicon has conducted Design FMEA's on their Prosima, Prolift and Prolift+M products. As part of Ethicon's safety analysis of these mesh products, they first developed a Qualitative and Quantitative Characteristics Worksheet to answer a number of critical

[52] *Guidelines for Failure Mode & Effects Analysis for Medical Devices*, p. 15-1.
[53] *Id* at p. 6-8.
[54] *Id* at p. 6-4.
[55] ISO 14971 Medical Devices – Application of risk management to medical devices, Second edition, 2007-10-01.
[56] ISO 14971 Medical Devices – Application of risk management to medical devices, Second edition, 2007-10-01.

questions about the product characteristics, including the mesh component. This worksheet serves to guide Ethicon employees and scientists in the creation of their design FMEA for each product. Some key questions from this worksheet that were not addressed correctly (answered as N/A or "not applicable") in order to consider oxidative degradation of the Prolene PP mesh are:[57]

- Are there any environmental factors that could influence safety/function of the device? N/A
- Are those components contacting biological materials compatible? N/A
- What is the effect of temperature on the system performance? N/A
- What is the effect of atmospheric gas concentration on system performance? N/A
- Is the device susceptible to environmental influences? N/A
- Do shipping temperatures affect device safety or functionality? N/A
- Does storage temperatures, humidity, or light affect device safety or functionality? N/A
- Does variation in the operating temperature, humidity, or light affect the device output or safety? N/A
- Is there any delayed or long-term user effect? N/A

All of these questions were answered incorrectly when properly considering the oxidative degradation properties of Prolene PP. All of these answers to their Qualitative and Quantitative Characteristics Worksheet as part of their safety analysis indicate that Ethicon did not and has not considered the oxidative degradation as a potential failure mode for these Gynemesh products. This is in direct contradiction of polymer literature on polypropylene oxidation, Ethicon's own internal studies, vendor MSDS sheets and external consultant studies.

Furthermore, Ethicon's design history files for the Prosima, Prolift and Prolift+M products provide a listing of potential hazards that is included as part Ethicon's safety analysis documents.[58] With the inclusion of this list in the design history files, Ethicon is asserting that this list was used to guide their safety analysis of these products. Key hazards included in this list are

- *Degradation*
- *Lack of adequate determination of end of device life*
- *Loss of mechanical integrity*
- *Likelihood of storage outside prescribed environmental conditions*

All of these suggested hazards for consideration should have triggered Ethicon's evaluation of oxidative degradation of their Prolene PP-based mesh used in their Prosima, Prolift and Prolift+M products.

[57] ETH.MESH.01962174-01962190, ETH.MESH.21989844-21990004, ETH.MESH.01154126-001154142
[58] ETH.MESH.21989844-21990004

Finally, and as a consequence of this inadequate safety analysis, Ethicon did not initially and has not to date considered oxidative degradation in any of its design FMEA's, which are their formal safety assessment document for the Prosima, Prolift and Prolift+M products. Again, the omission of oxidative degradation of Prolene PP fibers in the design FMEA's of these products is in direct contradiction of polymer literature on polypropylene oxidation, Ethicon's own internal studies, vendor MSDS sheets and external consultant studies. It is worth noting that all severities associated with failure of the mesh component as a result of any failure mode that was considered all result in high severities (8-10 on a 10 point scale).[59] Ethicon's description of their scale for severity rankings is included as Table 13 below.[60] Again, this indicates that Ethicon assesses that any failure of the mesh component of these devices results in severe harm to the implantee based on Ethicon's own assessment.

Table 13. ***Ethicon's Severity Ranking for Prolift+M dFMEA***

FMEA SEVERITY RANKING SCALE

NOTE: (F) denotes functional impact (A) denotes appearance impact

RANKING	DEGREE OF IMPACT
1	Improbable/Minor: Not perceptible or noticeable. (F) The consequences will not have any perceptible impact on the performance of the medical device. (A) The user will not notice the consequence.
2-3	Insignificant/Low, Negligible, Nuisance, Noticeable (F) Nuisance but likely negligible. (A) The user will probably notice only a minor negative impact on the medical device.
4-5	Moderately Significant/Dissatisfaction (A&F) The user will notice a negative impact as failure occurs, such as difficult to apply, difficult to use, discomfort, etc. (F) Partial loss of medical device operation or performs at a reduced level; possible gradual performance degradation.
6-7	Significant/High Annoyance (A&F) The failure causes greater annoyance to the user, such as creates pain. (F) Partial system function is lost, but the medical device can still be used without any safety concern.
8	Extreme/Very High: System function is lost (F) The medical device cannot be used, but failure does not create a safety, non-compliance or regulatory issue.
9	Almost catastrophic: Hazardous with warning (F) Medical device failure involves safety, non-compliance and/or regulatory issue. The user is forewarned that medical device failure is occurring.
10	Catastrophic: Hazardous without warning (F) Medical device failure involves safety, non-compliance and/or regulatory issue. The user is NOT forewarned that medical device failure is occurring.

ISO 14971 Medical Devices – Application of risk management to medical devices provides the necessary guidance for conducting the risk analysis of a new medical device. Furthermore, ISO 14971 clearly lists *chemical degradation* as one of its examples of initiating events and circumstances in ***Annex E: Examples of hazards, foreseeable sequences of events and hazardous situations***. This was not considered by Ethicon in their FMEA. Furthermore, ***Annex C: Questions that can be used to identify medical device characteristics that could impact on safety*** lists the following questions that should have further influenced Ethicon to fully assess chemical degradation of the Prolene polypropylene mesh used in their products.

[59] ETH.MESH.12288401-12288405
[60] ETH.MESH.02134781-02134783

C.2.2 Is the medical device intended to be implanted?
Factors that should be considered include *the location of implantation*, the characteristics of the patient population, age, weight, physical activity, *the effect of ageing on implant performance, the expected lifetime of* the implant, the reversibility of the implantation.

C.2.4 What *materials or components are utilized* in the medical device or are used with, or are *in contact with, the medical device*? Factors that should be considered include:
– *compatibility with relevant substances;*
– *compatibility with tissues or body fluids;*

C.2.21 Are there any *delayed or long-term use effects*?
Factors that should be considered include ergonomic and cumulative effects. Examples could include pumps for saline that corrode over time, mechanical fatigue, loosening of straps and attachments, vibration effects, labels that wear or fall off, *long term material degradation.*

2.0 Ethicon Quality Systems and Risk Assessment

2.1 Ethicon Failed to Provide Feedback to Their FMEA

As part of the design process, design engineers and other members of a design team must use the FMEA and other tools available to them to assess all foreseeable issues with the launch and sale of the product. Using these tools ensures that the procedures in place and quality systems are robust enough to appropriately handle, investigate, and proactively address any issues that relate to their devices.

The evidence in this case demonstrates that the design documents did not contemplate several FMEA issues and that Ethicon did not have an adequate quality system in place to address complaint handling, investigation, and appropriate responses to patient complications and other issues as they relate to oxidative and other changes to the meshes found in these POP products.[61] As a result, Ethicon was not appropriately funneling information into the FMEA process, thus failing to meet basic requirements thereof, which places implantees at risk for failures that are not being assessed or mitigated by the company. This is a fundamental breakdown of how an FMEA risk analysis is conducted, and an FMEA created for medical devices is no different; [62] [63]failing to adequately assess and monitor potential failure modes of any engineered product is a flaw to ensuring the safety and efficacy of that device.

In addition, long-term storage of the raw material used to create these meshes prior to extruding the monofilament fibers poses substantial oxidation concerns. As a supplier of permanently implantable medical devices, by failing to control its resin and eventual processing of these meshes with respect to polypropylene's inherent tendency to oxidize, Ethicon has failed to account for the risk associated with its degradation during manufacturing and storage for all those who buy, implant or are implanted with these products.

All of these things and more are evidence that the Quality Systems at Ethicon are inadequate.

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[61] ETH.MESH. 00259473, ETH.MESH.00302411, ETH.MESH.00349122; ETH.MESH.05644163; ETH.MESH.02157879; ETH.MESH.02017169; ETH.MESH.03924557; ETH.MESH.00870466; ETH.MESH.07429428; ETH.MESH.02134849; ETH.MESH.04038032; ETH.MESH.21989844
[62] ISO 14971 Medical Devices – Application of risk management to medical devices, Second edition, 2007-10-01.
[63] ETH.MESH.03742864

2.2 Ethicon Internal Studies Showed Oxidative Degradation of their Prolene Polypropylene

Ethicon observed evidence of PP oxidation and degradation in their own internal studies starting in the 1980's. At many points in time since first studying explanted material, Ethicon scientists have concluded that Prolene is vulnerable to oxidative changes inside the body—particularly in regards to the surface of the material as previously discussed in the polymer failure analysis part of this report.

2.3 Ethicon Failed to Update the Prosima, Prolift and Prolift+M's Risk Assessment with Known Failure Modes.

Ethicon observed the oxidative degradation of their Prolene polypropylene as early as the 1980's. As explained previously, as long as there is a source of oxygen, all polypropylene will be susceptible to oxidative changes, whether the polymer is implanted in a human being or if it is being stored at room temperature. This potential for oxidative degradation of Prolene polypropylene mesh was again reiterated to Ethicon through a technical review "Investigating Mesh Erosion in Pelvic Floor Repair.[64] This technical review was performed by PA Consulting Group at the request of Ethicon.

Furthermore, Ethicon's internal Prolene explant studies and other evidence of oxidation should have made the company aware that it had additional obligations to perform more testing before implanting these POP products into women. At no time that I am aware has the potential failure mode of "oxidative degradation" of the Prolene component of the Prosima, Prolift and Prolift+M products ever been considered and documented in Ethicon's failure mode and effects analysis.

2.4 Ethicon's Prosima, Prolift and Prolift+M Devices are Defective Designs

The Prosima, Prolift and Prolift+M device are defective designs since they each contain Prolene polypropylene, a material that is highly susceptible to oxidation. All mesh components in every Prosima, Prolift and Prolift+M device have this design flaw. Ethicon was aware of the potential for oxidation degradation of Prolene polypropylene and their own internal studies and testing indicated that this degradation was indeed occurring. Ethicon was aware that this resulted in polypropylene fiber embrittlement and cracking and a loss of fiber strength. Furthermore, Ethicon did not initially, or at any later point, include the oxidation of the mesh component of their Prosima, Prolift and Prolift+M devices after implantation as part of their safety analysis (FMEA) of these products. Failure to do this has resulted in the implantation of defective devices in patients. Identification of this design defect in the mesh component of the Prosima, Prolift and Prolift+M products was both foreseeable and avoidable.

VII. FACTS OR DATA CONSIDERED IN FORMING OPINIONS

The opinions and the bases for those opinions are set forth above. In addition to my knowledge, skill training and experience as an engineer, the following depositions of Ethicon employees and the exhibits thereto were supplied to me: Cliff Volpe, Piet Hinoul, David Robinson, Sunny Rah, Aaron Kirkemo,

[64] ETH.MESH.03750936-03750937

Sean O'Bryan, Scott Ciarrocca, Vincenza Zaddem, Elizabeth Vailhe, Christophe Vailhe, Joerg Holste, Boris Batke, Daniel Burkley, Thomas Barbolt, Brigitte Hellhammer, Juergen Trzewik, Martin Weisberg, Axel Arnaud, Dan Smith, Prof Thomas Muehl, Dr. Bernd Klosterhalfen, Kevin Ong, Whenxin Zheng, Daniel Sexton, and Jeffrey Brent.

I have also considered the following material identified in Exhibit B.

In addition, the following reports were supplied to me: Dr. Howard Jordi, Dr. Scott Guelcher, Prof Thomas Muehl, Prof. Bernd Klosterhalfen, Thomas Barbolt, Dr. Wenxin Zheng, and B. Todd Heniford, M.D. The findings of these experts are consistent with my opinions.

VIII. EXHIBITS WHICH I PLAN TO USE AS A SUMMARY OF OR IN SUPPORT OF OPINIONS

All the Exhibits which I plan to use as summary of or in support of my opinions have not yet been determined, but they include, but are not limited to:

1) Exhibits extracted from the materials I have reviewed;

2) Excerpts from learned treatises and literature;

3) Materials listed above;

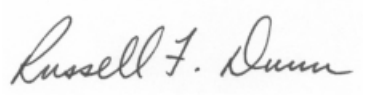
Any additional materials to be used will be timely disclosed.

IX. COMPENSATION AND TIME

A fee schedule for work on this case is attached as Exhibit C.

X. LISTING OF CASES IN WHICH TESTIMONY HAS BEEN GIVEN IN THE LAST FIVE YEARS

Please see Exhibit D.



Russell F. Dunn, Ph.D., P.E.
President
Polymer & Chemical Technologies, LLC

February 1, 2016

EXHIBIT B

degradation in this analysis.

BY MR. DAVIS:

Q. Have you considered any of Ethicon's biocompatibility risk assessments?

A. Yes. I've looked at their biocompatibility testing. I've looked at a lot of their testing. I'm telling you they did not consider oxidative degradation in this risk analysis. And that's clearly evident by the listing of questions that I provided in my report.

Q. Do you know who Thomas Barbolt is?

A. Yes. I've heard his name.

Q. I mean, I saw his name listed at the very end of your report, among a lot of other names.

A. Yes.

Q. Your report on the second-to-last page says that you were supplied a number of depositions, correct?

A. Yes. Some time ago, yes.

Q. Did you read any of those depositions in connection with your preparation of your current report?

A. At some point I have.

Q. Well, which ones did --

EXHIBIT C

Because products are used in different applications. You would have to test it in a similar circumstance to that application.

Q. Well, just make sure this is clear.

Do you know of any written standard adopted by the medical device industry for testing a medical device for oxidative degradation effects?

A. Well, you keep saying a "standard," and I would say that no such thing would exist. And that doesn't preclude a company from being responsible for testing for that effect.

Q. Okay. I notice in your report you talk about Ethicon's quality systems.

Do you recall that?

A. Yes, I do.

Q. And are there any written standards for quality systems for medical device manufacturers?

A. I understand that you want to use the term "standard."

There are guidelines and there are principles that are taught for quality systems. There are standards that have to do with risk analysis that would apply to medical devices, and that would affect some of the quality systems.

Q. Well --

A. What you are referring to would be something very specific that can't be applied across many different companies that are all operating in different ways.

But there are things outside of standards. There are engineering principles and there are guidelines provided. You just keep using the word "standards." And standards are not written for the quality systems, as -- as you've talked about, other than the ISO 14971 that has implications on quality.

Q. Okay. We'll get back to ISO 14971.

A. Uh-huh.

Q. I do have some questions about that.

But, aside from that written standard, do you know of any other written standards specific to the medical device manufacturing industry for quality systems, just specific to that industry?

A. I don't know that I've looked at -- specifically for a standard for quality systems for medical devices.

Q. So, when you express your opinions in this case regarding Ethicon's quality systems, what -- it sounds like you're just relying on some general principles that you go by in your

profession?

MR. BOWMAN: Object to form.

BY MR. DAVIS:

Q. Let me -- let me strike that and ask it over.

Just please explain to me the standards or the guidelines that you applied in this case, the principles that you applied in this case in developing an opinion that Ethicon's quality systems were less than satisfactory.

A. Okay. The -- the -- the implication you've made is that, when we're designing or when you have quality systems, that all goes back to standards.

I teach all of the chemical engineering seniors at Vanderbilt University, and I teach a course called "Product and Process Design." It is not a course on standards. We have a full textbook of guidelines and principles. It is not built on standards. It's built on engineering fundamentals and principles that we follow in designing products and having quality systems.

And even courses that you take on quality and quality engineering are not based on standards. We teach engineering principles. And

to suggest that, if it's not in a standard, it's -- it's not scientific or it's not based on scientific principles, does not represent what standards are intended for.

Q. Okay. Have you ever heard of 21 CFR Part 820?

A. I don't know.

Q. Okay. I mean, you don't know what it is, do you?

A. Not from memory.

Q. Okay.

A. I know it's Code of Federal Regulations, and 21 represents the department that it would be associated with. I can't recall -- 19 is OSHA. I can't recall which particular division that is of the Code of Federal Regulations. I don't have that one memorized --

Q. Well --

A. -- whether I've seen it or not.

Q. I'm sorry. I apologize. I interrupted you.

Were you through?

A. Yes.

Q. Okay. Well, with respect to the Code of Federal Regulations, you mentioned OSHA.

the body?

A. I agree that I am qualified to tell you the effects of oxidative degradation on the polymer itself and how it changes the polymer properties. And I agree that Dr. Guelcher is the expert that I work with who can tell you the effect on the body.

Q. Well, I appreciate that. But I just have a very simple question. If you'll just answer it, I'll move on.

Will you agree that you personally are not qualified to evaluate the effects or potential effects of oxidative degradation of Prolene on the body, the human body?

A. I -- I will reiterate that I can -- I am qualified to talk about the changes in the polymer properties --

Q. That's not my question. I'm sorry to interrupt you, but. . .

A. I would defer that to Dr. Guelcher.

Q. So the answer to my question? Yes?

A. No, the answer to your question is to an extent.

Q. Well -- okay.

A. I know you think it's a simple question, but, if I don't think it's a simple

question, then we disagree.

Q. Do you know what fault class the potential failure mode of oxidative degradation of Prolene in the body would be?

A. The fault class --

Q. Yes.

A. -- is -- if I'm not mistaken, that is a specific term that -- classification that Ethicon has come up with.

Q. Well, what classification is it?

A. Doesn't matter to me. That's not part of the failure mode and effects analysis. Once you get the risk priority number, you don't have to put in a fault class. You've got severity, you've got occurrence, you've got detection.

If a company wants to further define it and put it in a fault class, that's something they're doing internally.

Q. What -- what is the severity ranking, in your view, for oxidative degradation as a failure mode in Prolene?

A. Okay. I'm going to back up one more step. And I'm going to tell you that, as I teach the students and the students work in groups and do failure mode and effects analysis, I can tell you

what my severity ranking -- you come up with that ranking collectively with expertise from a lot of different areas.

You're asking me to rank it just with my background and experience, and I'm telling you that's not how a safety analysis or a failure mode and effects analysis takes place.

In fact, if you look at the top of Ethicon documents, you'll see that it's a whole team that's in there and talking. So it would be a team that's sitting around that would say, how do we want to rank that severity? And we would have a discussion on what is that effect and what implications would it have.

I can tell you what happens to the polymer, and I would hope that a medical -- a medical device person or a medical doctor would say, oh, if the polymer gets hard and brittle, I see the harm as being the following.

Q. While I'm on that Exhibit 7, I noticed -- I'm just trying to make sure I understand all the documents you reviewed.

Look at the last page of Exhibit 7.

MR. BOWMAN: Is that the FMEA?

MR. DAVIS: Yes.

THE WITNESS: Yeah. I got it. I've got it here.

Yes?

BY MR. DAVIS:

Q. I just saw that list of documents.

Did you review all those documents?

A. I don't know.

Q. Well, I mean, did you -- well, okay, let me ask this about Exhibit 7: Did you sit down and read the entire dFMEA, Exhibit 7?

A. I believe I did.

Q. Well, the reason I ask, is I notice -- if you look at your report, you have a -- you have a table, Table 5.

Can you look at Table 5 in your report?

A. Yes.

Q. Is that an excerpt from Exhibit 7?

A. It is indeed.

Q. Okay.

A. And you will find the entire Exhibit 7 in my footnote --

Q. Okay.

A. -- notebook.

Q. Okay. Well, I mean, I've -- I've read some of your prior testimony where you've indicated

that you've gotten to where you can read these FMEAs and -- fairly quickly and go to the heart of what you're looking for.

Is that a fair assessment?

A. I believe I can, yes.

Q. Okay. What I'm trying to say, is that what you did in this case? Did you simply pick up Exhibit 7 and -- and search for all the references to mesh?

A. Well, it -- the spreadsheet was set up by Ethicon that you could search by component. Because the mesh component -- while I looked at the other components, while the mesh component is the component comprised of polypropylene and the component that I'm interested in, I looked at the other areas, but I very specifically looked at mesh.

Because, if you're going to consider oxidative degradation of the mesh, it wouldn't be listed on another component; it would be listed on mesh.

Q. And that's what I'm trying -- I'm just trying to understand. Was there any reason for you to read the entire dFMEA, Exhibit 7, or did you simply get on the native version and search for

mesh?

A. No. I -- okay. So I read the entire FMEA at least from a component standpoint in looking at the various components and whether or not that related to something I needed to look across the row at.

Q. Okay. Well -- and, again, I'm just trying to -- looking back at the last page of this.

As an example -- I'm trying to understand, like, did you ever -- did you read that page, for instance, in your work on this case?

A. Did I see this page? Yes, I saw this page.

Q. And did you read this page? Did it matter to you?

MR. BOWMAN: Object to form.

THE WITNESS: Did it matter to me?

BY MR. DAVIS:

Q. Did it have any significance to you?

MR. BOWMAN: Same objection.

THE WITNESS: I -- it had significance insofar as it states that it's documents referenced in the body of the FMEA.

BY MR. DAVIS:

Q. Okay. I'm -- I'm just trying to

understand, for instance, did you try to then go find or ask for all these documents, or not?

A. Not that I recall, because these were referenced in the FMEA, and what I was interested in was what was not included in the FMEA.

Q. Okay. Do you have any experience in developing quality systems for medical devices?

A. Well, the FMEAs -- that's a hard question for me to answer. I haven't -- I teach FMEAs, and I teach it to students who end up working in all kinds of areas. So -- I haven't applied it in a specific company, but I teach these concepts to students that go out and work for medical companies and. . .

Q. Have you ever taught about how to develop quality systems specifically for medical devices?

A. I teach generically how to do product and process design, and it's applied by chemical engineers to numerous industries. I don't teach about a specific industry.

Q. What -- what does "design controls" mean? I mean specifically for medical devices.

A. It would be parameters that you establish that you want to control those

characteristics.

Q. Okay. What -- what are the design controls generally accepted for medical devices?

A. It would be different for different medical devices.

Q. Can you -- can you just tell me what some of the design controls are for medical devices?

A. Oh. Well -- so, if I talked about the mesh component, because that's the component that I'm looking at for the medical device for the Prosima, certain design controls would be things like the weave, the diameter of the fiber, the density.

Q. That --

A. You're shaking your head no.

Q. Maybe we're on a different wavelength, because I'm asking you -- the process, the process of design controls, in designing and developing a medical device. Can you tell me what the design control processes are?

A. You're going to have to ask a -- I don't know what you're asking exactly.

Q. That's fair enough.

Do you have any experience in

maintaining a quality system for medical devices in particular?

A. It's no different for medical devices than other devices.

Q. So is the answer you don't have any specific experience for medical devices, or you do? Either you do or you don't.

A. I've never manufactured medical devices.

Q. So you've never had any experience in maintaining a quality system for medical devices; is that correct?

A. But I maintain that the quality systems I've been involved in in my work career are the same as those types of systems you'd put in place for medical devices.

Q. With that explanation, is the answer yes?

A. Ask the question again now.

Q. Have you ever had any experience in maintaining a quality system for a medical device in particular?

A. Not specifically for a medical device, but quality systems that I've maintained and been involved in in manufacturing operations are -- are

the same or very similar.

Q. Have you ever had any experience in auditing quality systems for medical devices?

A. Not specifically medical devices. Only other polymer-based products.

Q. And can you give me an overview of how you performed your audits?

A. Of other polymer products?

Q. Yes.

A. Sure. You -- you asked a question before that I guess I misinterpreted about design controls. So -- in auditing polymer-based products that I've been involved in and that we would manufacture, we had certain specifications or criteria, what I would call design controls. Certain parameters that you could measure that you were trying to target in the manufacturing process.

In -- in trying it maintain a quality system, you would go and pull random samples and test those versus your design controls.

Q. Okay.

A. If I'm understanding the question correctly.

Q. Now, do you have any experience in preparing any design controls for medical devices?

For the design and development of medical devices, that is.

A. Not specifically for medical devices; only for other polymer-based products.

Q. Okay. And what were those design controls?

A. For other polymer-based products?

Q. Yes.

A. They varied, depending on what the product was.

Q. Okay. I know it's your testimony, your opinion, that Ethicon's Prolene is subject to oxidative degradation.

I'd like to follow up on that and ask you, are there any degradation products of the oxidative degradation of Prolene?

A. Not typically. It -- the oxidative -- oxygen -- it -- it -- it depends on how it oxidizes. I need to be careful with that, because there's different oxidizing agents that can react with it. And, depending on the oxidizing agent that reacts with it, I think there can be some potential for byproducts.

In general, oxygen is attaching from some type of reactive oxygen species or even oxygen

from the air, and it breaks the chain, the long chain length of the polypropylene, into shorter chains.

Q. In that case, let's focus on Prolene in the body specifically.

A. Okay.

Q. Are there -- I know you've given the opinion that, in the body, there is oxidative degradation going on of the Prolene.

So I want to know, are there any degradation products resulting from the oxidation that -- degradation that you believe is occurring?

MR. BOWMAN: Object to form.

THE WITNESS: Can you point to in my report where I say that it's oxidizing in the body?

You said I said that it oxidized in the body. That's what -- there are reactive oxygen species in the body, but that specifically -- that oxidative mechanism inside the body is specifically what Dr. Guelcher reports on.

BY MR. DAVIS:

Q. Okay. You don't have an opinion as to whether Prolene oxidizes in the body --

MR. BOWMAN: Object to form.

BY MR. DAVIS:

Q. -- is that correct?

A. No, that's not correct.

Q. Okay. Do you -- is it your opinion that Prolene, after implantation in the human body, is undergoing oxidative degradation?

MR. BOWMAN: Object to form.

THE WITNESS: Yes.

BY MR. DAVIS:

Q. Okay. And where is that in your report? I thought a minute ago you said -- you said it's not in your report.

A. It's not. I don't offer that as an opinion, and I'm not going to testify on that. But you asked if I believed that's happening. And, yes, I do believe that's happening.

Q. Okay.

A. But, the actual mechanism for how it's happening -- I say that because I've read Dr. Guelcher's report.

Q. Okay. But -- so -- my question then -- follow-up -- is, will you agree that it's not within your expertise to evaluate whether Ethicon's Prolene is undergoing oxidative degradation after implantation in the body?

MR. BOWMAN: Object to form.

THE WITNESS: Not the way that you worded that question, no, I don't agree with that.

BY MR. DAVIS:

Q. How did you -- how would you word it?

A. I'm not wording the question. I'm answering your question. So if you want to read it back, I'll answer it specifically.

Q. Okay. What expertise do you have to evaluate whether Ethicon's Prolene is undergoing oxidative degradation within the human body?

A. Okay.

MR. BOWMAN: Object to form.

THE WITNESS: I have expertise of what Prolene does outside the body and how it oxidizes. I have expertise on testing for oxidation.

BY MR. DAVIS:

Q. Outside the body, right?

A. Outside the body, or even something that was inside the body and then was taken out of the body. The testing is the same for that.

So I have expertise on testing even something that's come out of the body -- you asked if I had any expertise to see if it's oxidized in the body. You can take explants and you can do

testing and you can see if oxidation has occurred. And I have expertise in doing that and evaluating that.

Q. Have you done it in this case?

A. I do not have explants in this case, no.

Q. Okay. Do you know who the -- the name of the plaintiffs in this case are?

A. Jasso.

Q. Okay. Do you know anything about her?

A. I do not.

Q. Do you know what she had implanted in her?

A. I don't have any specific information about the plaintiff. I'm assuming it's a Prosima because that's what I was asked to evaluate for this case. But I was not asked to evaluate the effect in her body.

Q. Did you ask if any explants were available relating to Ms. Jasso?

By the way, I believe it's pronounced YAH-so.

A. Jasso.

Q. I may be wrong, but. . .

A. I don't recall if I asked that or not.

Q. Okay.

MR. LITZENBURG: I don't know if I can help to shortcut this at all, but Dr. Dunn will not be offered for any case-specific testimony --

MR. DAVIS: Okay.

MR. LITZENBURG: -- plaintiff specific.

MR. DAVIS: Thank you.

BY MR. DAVIS:

Q. Dr. Dunn, do you have any expertise on what occurs to Prolene within the body?

MR. BOWMAN: Object to form.

THE WITNESS: Yes.

BY MR. DAVIS:

Q. What is that expertise?

A. That, if it does oxidize, I know what the effect is on the polymer, the properties that it changes on the polymer, the molecular weight, the flexibility, that it goes from being ductile to being brittle, that it cracks, that it flakes.

Q. Well, but you started that with the word "if" it oxidizes, right?

A. Let's read back what your question was.

Can -- what was the last question I was asked?

(Whereupon the following question was

chemically in published literature, such as the fact that polypropylene has been known to oxidize for decades. So I agree.

Q. In fact, you -- in your own report, you -- you point out that polypropylene has been extensively studied since the 1960s, right?

A. Outside the body, yes.

Q. Okay.

Now, do you see where, at the bottom of page 3 of 6, the FDA goes on to explain that, in analyzing the need for biocompatibility testing, you should follow ISO 10993? Do you understand that?

A. Yes.

Q. And do you also --

A. Can -- I just want to point out one more time that biocompatibility and -- and chemical degradation were in different categories in the FMEA, and everything associated with biocompatibility that we're talking about was not in the category that I am discussing.

So continue on.

Q. Because you're saying that oxidative degradation is a chemical process, as opposed to -- as opposed to going to biocompatibility?

EXHIBIT D

LITERATURE

Author	Name	Journal Citation
Achimsky, L.	Kinetic Study of the Thermal Oxidation of Polypropylene.	Polymer Degradation and Stability 57:231-240 (1997).
Alajmo F	Polypropylene Suture Fracture2	Ann Thorac Surg 1985 39.4: 400
Aldrete V	Polpropylene Suture Fracture	Ann Thorac Surg 1984 Mar; 37(3):264
Altman AJ, Gorn RA, et al	The breakdown of polypropylene in the human eye: is it clinically significant?	Ann Ophthalmol 1986 May; 18(5) 182-5
Anderson	Cellular interactions with biomaterials: in vivo cracking of pre-stressed Pellethane	
Anderson JM, et al	Foreign Body Reaction to Biomaterials	Semin Immunol 2008 April; 20(2): 86-100
Apple DJ, Mamalis N, et al	Biocompatibility of implant materials: a review and scanning electron microscopic study	J Am Intraocul Implant Soc 1984 Winter; 10(1):53-66
Bachman, S, Ramshaw, B	Prosthetic Material in Ventrial Hernia Repair: How Do I Choose?	Surg Clin N Am 88 (2008) 101-112
Barbolt TA	Biology of polypropylene/polygiactin 910 grafts	Int Urgynecol J (2006) 17; S26-S30
Berrocal J, Clave' H, et al	Conceptual advances in the surgical management of genital prolapse The TVM technique emergence	J Gynecol Obstet Biol Reprod 2004: 33:577-587
Binnebosel M, et al.	Biocompatibility of prosthetic meshes in abdominal surgery	Semin Immunopathol. 2011; 33:235-243
Calhoun TR, Kitten DM	Polypropylene suture -- Is it safe?	J Vasc Surg 1986; 4:98-100
Chanda et al	Industrial Polymers	Hardcover 2008
Clarke KM, Lantz GC, et al	Intestine Submucosa and Polypropylene Mesh for Abdominal Wall Repair in Dogs	Journal of Surgical Research 60, 107-114 (1996)
Clave', A., et al	Polypropylene as a Reinforcement in Pelvic Surgery in Not Inert: Comparative Analysis of 100 Explants.	Int Urogyn J 2010; 21:261-270
Claymen HM	Polypropylene	Opthalmology 1981 88:959-976
Cobb, W., et al.	The Argument for Lightweight Polyropylene Mesh in Hernia Repair	Surgical Innovation 2005, 12(1):T1-T7
Cobb, WS, et al	Textile Analysis of Heavy Weight, Mid-Weight, and Light Weight Polypropylene Mesh in a Porcine Ventral Hernia Model	J Surg Research 136, 1-7 (2006)
Coda A	Structural alterations of prosthetic meshes in humans	Hernia (2003) 7: 29–34
Cornel G	Fracture of Polypropylene Suture	Ann Thorac Surg 1982; 33:641
Cosson M, et al	Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal materia;?	Int Urogynecol J (2003) 14: 169-178
Costello CR, et al	Materials Characterization of Explanted Polypropylene Hernia Meshes	J Biomed Mater Res Part B: Appl Biomater 83B: 44-49, 2007

LITERATURE

Author	Name	Journal Citation
Costello, C., et al	Characertization of Heavyweight and Lightweight Polypropylene Prosthetic Mesh Explants from a Single Patient.	Surgical Innovation. 2007; 14(3): 168-176
Cozad MJ, et al	Materials characterization of explanted polypropylene, polyethylene terephthaiate, and expanded polytetrafluoroethylene composites: Spectral and thermal analysis	J Biomed Mater Res Part B: Appl Biomater 94B: 455-462, 2010
Das N	Review Article: Microbial Degradation of Petroleum Hydrocarbons Contaminant: An Overview	Journal of Biotechnology Research International, Volume 2011, Article ID 941810
de Tayrac, R. & Letouzey, V.	Basic science and clinical aspects of mesh infection in pelvic floor reconstructive surgery.	Int Urogynecol J, 22(7), 775-780. doi: 10.1007/s00192-011-1405-4.
Drews RC	Polypropylene in the human eye	Am Intra-Occular Implant Soc J 1983 Spring 9:137-142
Falconer, C., et al	Influence of Different Sling Materials on Connective Tissue Metabolism in Stress Urinary Incontinent Women	Int Uyrogynecol J (2001) (Suppl 2):S19-S23
Fayolle B, Audouin L, et al	Macroscopic heterogeneity in stabilized polypropylene thermal oxidation	Polymer Degradtion and Stability 77 (2002) 515-522
Fayolle B, Audouin L, et al	Oxidation induced embrittlement in polypropylene -- a tensile testing study	Polymer Degradation and Stability 70 (2000) 333-340
Fayolle, et al	Initial steps and embrittlement in the thermal oxidation of stabilised polypropylene films	Polymer Degradation and Stability 75 (2002) 123-129
Feola A, Moalli PA, et al	Stress-Shielding the mpact of Mesh Stiffness on Vaginal Function	Female Pelvic Med Reconstr. Surgery (2011) 17(5): S54-S110
Feola, A.	Deterioration in biomechanical properties of the vagina following implantation of a high-stiffness prolapse mesh	BJOG An International Journal of Obstetrics and Gynaecology 2013
Frostling, H, et al	Analytical, occupational and toxicologic aspects of the degradation products of polypropylene plastics	Scand J Work Environ Health 1984; 10(3):163-169
Goretzlehner U, Mullen A	PVDF as an implant material in urogynaecology	Translation of German article accepted for publishing: Journal "Biomateriallen" ISSN 1616-0177
Greenwald D, Shumway S, et al	Mechanical Comparison of 10 Suture Materials Before and After in Vivo Incubation	J Surg Research 1994; 56:372-377
Guidoin R, Chakfe N	Aneurysmal Deteroration of Arterial Substitutes	Current Therapy in Vascular Surgery 2: 324-328
Hafeman AE, et al	Characterization of the degradation mechanisms of lysine-derived aliphatic poly (ester urethane) scaffolds	Biomaterials 32 (2011) 419-429

LITERATURE

Author	Name	Journal Citation
Heniford, B.T.	"""The benefits of lightweight meshes in Ventral Hernia Repair in Ventral Hernia Repair"""	Video produced by Ethicon. 2007
Hilton, P., et al	Postural Perineal Pain Associated With Perforation of the Lower Urinary Tract Due to Insertion of a Tension-Free Vaginal Tape	BJOG (2003) 110: 79-82
Hiltz, A.	Oxidative Degradation of Unstabilized Polypropylene.	Textile Research J. 35:716-724 (1965).
Hinoul P, Bonnet P, Krofta L,et al	An anatomic comparison of the original versus a modified inside-out transobturator procedure	Int.Urogynecol J(2011) 22(8) 997-1004
Hinoul P, Vervest HAM, et al	A Randomized, Controlled Trial Comparing an Innovative Single Incision Sling With an Established Transobturator Sling to Treat Female Stress Urinary Incontinence	The Journal of Urology, Vol. 185, 000, April 2011
Hiren, P, Osterguard DR, et al	Polypropylene mesh and the host response	Int Urogynecol J (2012) 23:669-679
Hoff	Thermal Oxidation of Polypropylene in the Temperature Range of 120-280C	J Appl Polym Sci 29:465-80,1984
Huber A, et al	Histopathologic hosts response to polypropylene-based surgical mesh materials in a rat abdominal wall defect model	J Biomed Mater Res Part B: Appl Biomater 100B: 709-717, 2012
Iakovlev V, Mekel G, Blaivas J	Pathological Findings of Transvaginal Polypropylene Slings Explanted for Late Complications: Mesh Is Not Inert	ICS.org abst 228 Study St Michael's Hospital, Univ. Toronto
Iakovlev VV, Carey ET, Steege J	Pathology of Explanted Transvaginal Meshes	International Journal of Medical, Health, Pharmaceutical and Biomedical Engineering Vol:8 No:9, 2014
Iakovlev	In vivo degradation of surgical polypropylene meshes: A Finding overlooked for decades	Virchows Arch (2014) 465 (Suppl 1):S1–S379
Iakovlev	Explanted surgical meshes: what pathologist and industry failed to do for 50 years	Virchows Arch (2014) 465 (Suppl 1):S1–S379
Iakovlev, V., Guelcher, S., and Bendavid, R.	Degradation of Polypropylene In Vivo: A Microscopic Analysis of Meshes Explanted from Patients.	Journal of Biomedical Materials Research: Part B - Applied Biomaterials. Manuscript ID: JBMR-B-15-0208.R1 (Accepted for Publication July 30, 2015).
Jongebloed, WL, et al.	Degradation of Polypropylene in the Human Eye: A Sem-Study	Doc Ophthalmol,Vol 64, No. 1, pp. 143-152, 1986
K. Junge, et al.	Elasticity of the anterior abdominal wall and impact for reparation of incisional hernias using mesh implants.	Hernia (2001) 5:113-118

LITERATURE

Author	Name	Journal Citation
Kausch HH	The Effect of Degradation and Stabilization of the Mechanical Properties of Polymers Using Polypropylene Blends as the Main Example	Macromol Symp 2005, 225: 165-178
Klinge U, et al	Shrinking of Polypropylene Mesh in vivo: An Experimental Study in Dogs*	Eur J Surg 1998; 164: 965-969
Klinge U, Klosterhalfen B, et al	PVDF as a new polymer for the construction of surgical meshes	Biomaterials 23 (2002) 3487-3493
Klosterhalfen B and Klinge U.	The lightweight and large porous mesh concept for hernia repair	Expert Rev. Med. Devices, 2005; 2(1)
Lacoste, J. et al.	Surface and bulk analyses of the oxidation of polyolefins.	Polymer Degradation and Stability 49 (1995) 21-28
Lacoste, J. et al.	Gamma-, Photo-, and Thermally-Initiated Oxidation of Isotactic Polypropylene.	J. Polm. Sci. A. Polym. Chem 31:715-722 (1993).
Liebert T., et al	Subcutaneous Implants of Polypropylene Filaments	J Biomed Mater Res. 1976; 10:939-951
Lithner D	Environmental and Health Hazards of Chemicals in Plastic Polymers and Products	University of Gothernburg Publishing
Martin JR, et al	A porous tissue engineering scaffold selectively degraded by cell-generated reactive oxygen species	Biomaterials 35 (2014) 3766-3776
Mary, Celine, et al	Comparison of the In Vivo Behavior of the Polyvinylidene Floride and Polypropylene Sutures Used In Vascular Surgery	ASAIO Journal 1998: 199-206
Moalli J, Editor	Plastics Failures, Analysis and Prevention	2001, Chapters 1 and 6
Ostergard DR	Degradation, infection and heat effects on polypropylene mesh for pelvic implantation: what was known and when it was known	Int Urgynecol J (2011) 22:771-774
Oswald JF, Turi E	The Deterioration of Polypropylene By Oxidative Degradation	Polymer Engineering and Science 5 (1965) 152-158
P. Bahadur, N.V. Sastry	Principles of Polymer Science	Principles of Polymer Science, 2nd Edition
Pandit AS, Henry, JA	Design of surgical meshes -- an engineering perspective	Technology and Health Care 12 (2004) 51-65
Postlehwait RW	Long-Term Comparative Study of Nonabsorbably Sutures	Ann Surg (1970) 171(6): 892-898
Postlethwait RW	Five Year Study of Tissue Reaction to Synthetic Sutures	Ann Surg 190(1):54-57 (1979)
Rene' de la Rie E	Polymer Stabilizers. A Survey With Reference to Possible Applications in the Conservation Field	Studies in Conservation 33 (1988) 9-22
Silva, RA, et al	Degradation Studies of Some Polymeric Biomaterials: Polypropylene (PP) and Polyvinylidene Difluoride (PVDF)	Materials Science Forum Vols. 539-543 (2007): 573-576
Sternschuss, G, et al	Post-Implantation Alternations of Polypropylene in the Human	J Uro 2012;188: 27-32

LITERATURE

Author	Name	Journal Citation
Szarnicki RJ	Polypropylene Suture Fracture	Ann Thorac Surg 1985 April; 39(4):400
Tzartzeva K, Lingam D, et al	In-Depth Nano-Investigation of Vaginal Mesh and Tape Fiber Explants in Women	Study: UT SW Med Center, UT Dallas
Williams D.	Review Biodegradation of surgical polymers	Journal of Materials Science. 1982; 17:1233-1246
Williams DF	There is no such thing as a biocompatible material	Biomaterials 35 (2014) 10009-10014
	EB-405, The Durability of Polypropylene Geotextiles for Waste Containment Application	Available at www.geotextile.com
CAW/TCA	Health, Safety and Environment Fact Sheet: Hazardous Substances - Plastics	Available at www.caw.ca
	Applied Plastics Engineering Handbook, Processing and Materials	2011
Scheirs	Compositional and Failure Analysis of Polymers	2000
	Polypropylene: The Definitive User's Guide and Databook	Harcover 1998
A Imel, T Malmgren, M Dadmun, S. Gido, J Mays	In vivo oxidative degradation of polypropylene pelvic mesh.	Biomaterials 73:131-141, 2015
	Plastics Additives Handbook 6th Edition	Hardcover 2009
Brydson	Plastic Materials	1999
Klinge U, Junge K, Stumpf M, Ap AP, Klosterhalfen B.	Functional and morphological evaluation of a low-weight, monofilament polypropylene mesh for hernia repair.	J Biomed Materials 21 Res. 2002;63:129-36.
Klinge U, Park JK, Klosterhalfen B	'The ideal mesh?'	Pathobiology. 2013;80:169-75.

DOCUMENTS

DATE	DOCUMENT	BATES BEG	BATES END
	TVT Abbrevo IFU	ETH.MESH.02341203	
9/22/1987	Lab Notebook pages from 1987 Study of Human	DEPO.Eth.Mesh.00000	
	Guidoin Explant Report	Depo.eth.mesh.00004 755	
	ASTM Standard Test Method for Stiffness of Fabrics	Designation: D 1388 – 96 (Reapproved 2002)	
0/0/2010	Richter NEJM article	Eth. Mesh.02594075	
		ETH.MESH . 00219861	
		ETH.MESH . 00748451	
		ETH.MESH . 00836161	
		ETH.MESH . 00870466	
		ETH.MESH . 01154126	
		ETH.MESH . 01962174	
		ETH.MESH . 02134849	
		ETH.MESH . 02157879	
		ETH.MESH . 02227368	
		ETH.MESH . 02282833	
		ETH.MESH . 03987419	
		ETH.MESH . 04013853	
		ETH.MESH . 04038032	
		ETH.MESH . 05644163	
	Risk Assessment	ETH.MESH . 06195201	ETH.MESH.06195205
		ETH.MESH . 06372356	
		ETH.MESH . 07726704	
		ETH.MESH . 07928207	

DOCUMENTS

		ETH.MESH . 07930355	
	Braskem MSDS	ETH.MESH . 10630803	ETH.MESH.10630808
		ETH.MESH . 11298411	
		ETH.MESH . 11298469	
		ETH.MESH . 11298478	
		ETH.MESH . 11298489	
		ETH.MESH . 11298513	
		ETH.MESH . 13345921	
		ETH.MESH . 14234636	
		ETH.MESH . 14234651	
		ETH.MESH . 14237478	
	Mesh Safety Report	ETH.MESH . 14442958	ETH.MESH.14442976
		ETH.MESH . 21989844	
		ETH.MESH . 21989844	
0/0/2012	Barber article	Eth.Mesh .10282645	
8/23/2007	Zaddem V email re macroporous - lower limit of pore size	ETH.MESH.00000272	ETH.MESH.00000272
8/9/2005	Selman 2005 Performance and Development Plan Summary	ETH.MESH.00000298	ETH.MESH.00000364
9/22/1987	Lab Notebook pages Re Prolene Explants	ETH.MESH.00000367	ETH.MESH.00000368
11/22/2007	Performance Qualificagtion Protocol: Gynecare Prolift +M Sous-Ensemble	ETH.MESH.00000428	ETH.MESH.00000428
3/5/2009	Interim report mesh explants pelvic floor repair	Eth.Mesh.00006636	
04/??/08	Klosterhalfen Interim report mesh explants pelvic floor repair	ETH.MESH.00006636	ETH.MESH.00006636
	Presentation: Stand & Deliver Pelvic Floor Repair	ETH.MESH.00006796	ETH.MESH.00006809
11/18/2008	Pelvic Floor Repair Online Training Course Second Draft Content Document	ETH.MESH.00008072	ETH.MESH.00008072
	Annotated Prolift +M List of potential claims	ETH.MESH.00008631	ETH.MESH.00008631
	Cosson, et al, Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal material? Int. Urogynecol J (2003) 14: 169-178	Eth.Mesh.00015598	Eth.Mesh.00015607
12/8/2003	510(k) Summary	ETH.MESH.00019863	ETH.MESH.00019924
11/28/2005	510(k) premarket notification letter	ETH.MESH.00019925	ETH.MESH.00020019
	Gynecare Prolift Pelvic Floor Repair System presentation	ETH.MESH.00033325	ETH.MESH.00033385
	Dr Lucent session transcript	ETH.MESH.00067356	ETH.MESH.00067363
	Medical Device Risk Management Plan - Revision Hx for PR602-003 Rev 13	ETH.MESH.00070187	ETH.MESH.00070211

DOCUMENTS

1/5/2010	Timoner Fortin, S email chain re Prosima learning's at preceptor sites EMEA	ETH.MESH.00077727	ETH.MESH.00077732
3/7/2007	Flatow J email chain re Lightning 510(k) requirements list	ETH.MESH.00078537	ETH.MESH.00078539
6/29/2010	Clinical Study Report A Prospective, Multi-centre Study to Evaluate the Clinical Performance of the Gynecare Prolift +M Pelvic Floor Repair System as a Device for Pelvic Organ Prolapse	ETH.MESH.00080795	ETH.MESH.00080924
??/??/07	Prolift +M IFU	ETH.MESH.00081133	ETH.MESH.00081139
11/9/2010	11/9-11/2010 AAGL Meeting PPT Presentation.	Eth.Mesh.00107688	
11/9/2011	AAGL Las Vegas meeting brochure	ETH.MESH.00107688	ETH.MESH.00107688
	TVT Professional Education Program	ETH.MESH.00156909	ETH.MESH.00156938
??/??/06	No bigger than your palm - brochure	ETH.MESH.00158289	ETH.MESH.00158293
	Memorandum re Copy review submission compliance	ETH.MESH.00159473	ETH.MESH.00159473
5/4/2007	Gynecare TVT Secur System: Key Technical Points	ETH.MESH.00163952	ETH.MESH.00163960
4/18/2006	CER Weisberg - Laser Cut Mesh	ETH.MESH.00167104	ETH.MESH.00167110
2/8/2002	Design Validation Strategy Version 1	ETH.MESH.00199408	ETH.MESH.00199413
11/24/2005	Team conference call notes	ETH.MESH.00208897	ETH.MESH.00208897
11/10/2009	Mini TVT-O Team Meeting	Eth.Mesh.00211038	Eth.Mesh.00211041
11/10/2009	Mini TVT-O Team Meeting Agenda	ETH.MESH.00211038	ETH.MESH.00211041
1/8/2002	Barbolt memo to D'Aversa re Biocompatibility Risk Assessment for Prolene	ETH.MESH.00220333	ETH.MESH.00220336
5/14/2001	TVT-O Design History Book 5 of 7	ETH.MESH.00222779	ETH.MESH.00223267
	TVT-O Design History Book 5 of 7	Eth.Mesh.00222779	
5/14/2001	TVT-O Design History Book 1 of 7	ETH.MESH.00259047	ETH.MESH.00259514
	TVT-O Design History Book 1 of 7	Eth.Mesh.00259047	
12/15/2003	Product Design Safety Assessment Revision 2	ETH.MESH.00259473	ETH.MESH.00259503
5/29/2003	Study description Chart	ETH.MESH.00260020	ETH.MESH.00260021
4/14/2003	Smith,D email chain re Mulberry update	ETH.MESH.00260591	ETH.MESH.00260592
0/0/2003	Email re: lack of clinical data	Eth.Mesh.00260591	
6/9/2003	O'Bryan S email re Mulberry stage gate action item closed	ETH.MESH.00261584	ETH.MESH.00261585
	PPT Presentation titled “The Science of What’s Left Behind: Evidence & Follow-Up of Mesh Use for SUI.”	Eth.Mesh.00271641	
	Nick Franco Naples, FL Presentation: The Science of "What's Left Behind"... Evidence & Follow-Up of Mesh Used for SUI	ETH.MESH.00271641	ETH.MESH.00271641
11/21/2005	Email re: GREAT NEWS FOR TVT LASER CUT MESH!	Eth.Mesh.00301741	Eth.Mesh.00301742
11/21/2005	Lamont D email chain re Great News for TVT Laser Cut Mesh	ETH.MESH.00301741	ETH.MESH.00301742
2/24/2006	Lamont D Memo re TVT Laser Cut Mesh Risk Analysis Summary	ETH.MESH.00302105	ETH.MESH.00302106
2/20/2007	Lamont D email chain re Complaint Summaries	ETH.MESH.00303084	ETH.MESH.00303085
3/5/2008	Lamont D email chain re Gynemesh issue	ETH.MESH.00303944	ETH.MESH.00303945

DOCUMENTS

4/29/2008	Lamont D email chain re Post Launch Reviews	ETH.MESH.00304013	ETH.MESH.00304014
		ETH.MESH.00308747	
3/3/2008	Robinson D email chain re Quality issue with a batch of gynemesh	ETH.MESH.00328895	ETH.MESH.00328901
	- DFMEA	ETH.MESH.00335080	ETH.MESH.00335080
12/18/2008	Lisa B email chain re TVT Patient Brochure Fair Balance EPI Changes	ETH.MESH.00339083	ETH.MESH.00339084
02/??/02	5 Years of Proven Performance	ETH.MESH.00339437	ETH.MESH.00339442
4/1/2009	Email re: TVT-Mini Clinical Support.	Eth.Mesh.00346227	
4/1/2009	Lisa B email re TVT-Mini clinical support	ETH.MESH.00346277	ETH.MESH.00346277
	Excel Spreadsheet of Pain associated with TVT-O.	Eth.Mesh.00354725	
	Spreadsheet re TVT-O pain	ETH.MESH.00354725	ETH.MESH.00354725
??/??/10	pg from Minimally invasive synthetic suburethral sling operation for SUI in women	ETH.MESH.00355087	ETH.MESH.00355087
		ETH.MESH.00360799	
	Revision Hx for PR800-012 Rev 11	ETH.MESH.00363605	ETH.MESH.00363625
1/28/1998	510(k) clearance letter	ETH.MESH.00371496	ETH.MESH.00371594
2/1/2006	Global Regulatory Strategy GYNECARE TVT - Laser Cutting Project	ETH.MESH.00394544	ETH.MESH.00394553
5/6/2005	London Brown A email re Laser-cut Mesh	ETH.MESH.00526473	ETH.MESH.00526474
6/23/2006	St. Hilaire P email chain re LCM - Launch Strategy EMEA	ETH.MESH.00526484	ETH.MESH.00526487
5/22/2007	Smith D email chain re TVT Secur EU Experts meeting - feedback & future action	ETH.MESH.00527832	ETH.MESH.00527836
9/27/2010	Shah N email chain re Textile supplier	ETH.MESH.00528621	ETH.MESH.00528626
11/18/2003	Wesiberg Memo to File re Mesh Fraying for TVT Devices	ETH.MESH.00541379	ETH.MESH.00541380
10/18/2010	Caro-Rosado L email chain re Lab results orf Mesh roping evaluation	ETH.MESH.00544657	ETH.MESH.00544658
5/18/2006	Cantimbuhan R email re design transfer checklist dicussion, 05/16/06	ETH.MESH.00554680	ETH.MESH.00554680
2/15/2006	Flatow J email chain re DVer protocol for particle loss	ETH.MESH.00584291	ETH.MESH.00584292
6/6/2006	Fournier H re New Standards for Urethral Slings	ETH.MESH.00584488	ETH.MESH.00584494
6/6/2006	Fournier H re New Standards for Urethral Slings	ETH.MESH.00584491	ETH.MESH.00584497
2/19/2004	Email thread re: Prolene Mesh.	Eth.Mesh.00584714	
2/19/2004	Kammerer G email chain re Prolene Mesh	ETH.MESH.00584714	ETH.MESH.00584715
4/19/2004	Kammerer G email re Ultrasonic Slitting of Prolene Mesh for TVT	ETH.MESH.00584811	ETH.MESH.00584813
3/10/2006	Next Generation Mesh Discussion Agenda	ETH.MESH.00585672	ETH.MESH.00585673
5/9/2006	Email re: Particle Loss on TVT	Eth.Mesh.00585802	
5/9/2006	Kammerer G email re Particle loss of TVT	ETH.MESH.00585802	ETH.MESH.00585802
6/12/2006	Kammerer G email chain re TVT LCM - particle loss (reimbursement submission)	ETH.MESH.00585842	ETH.MESH.00585843

DOCUMENTS

1/20/2006	Kammerer G email chain re TVT - TVT-O specifications	ETH.MESH.00585906	ETH.MESH.00585909
2/13/2006	Kammerer G email chain re TVM discussions	ETH.MESH.00585937	ETH.MESH.00585939
3/28/2007	Performance Evaluation Technical Report	ETH.MESH.00593165	ETH.MESH.00593189
	PPT Slides "TVT Abbrevo U.S. Launch Overview."	Eth.Mesh.00632655	
	U.S. Launch Overview	ETH.MESH.00632655	ETH.MESH.00632655
		ETH.MESH.00684368	
12/19/2005	Mahar K mail chain re Lazer cut mesh	ETH.MESH.00687819	ETH.MESH.00687822
12/19/2005	Mahar K email chain re Lazer cut mesh	ETH.MESH.00687819	ETH.MESH.00687822
12/21/2005	Honjnoski P email chain re CER - LCM	ETH.MESH.00700344	ETH.MESH.00700345
10/5/2006	Hernandez J email re TVT LCM Early EU Feedback	ETH.MESH.00746204	ETH.MESH.00746208
??/??/06	Product Pointer	ETH.MESH.00746209	ETH.MESH.00746209
	Surgeon Evaluation Questions for Laser Cut Mesh	ETH.MESH.00746210	ETH.MESH.00746212
11/9/2010	TVT Classif IFU Revision Project Design Requirements Waiver Rationale Memo	ETH.MESH.00748213	ETH.MESH.00748213
5/15/2008	Prolift +M FDA Clearance Letter	ETH.MESH.00748451	ETH.MESH.00748803
8/23/2005	Final Report, PSE Accession Number 05-0395, Project Number 67379	ETH.MESH.00749504	ETH.MESH.00749517
3/9/2006	Interim Report Test and Control ARticle Material Characterization Program	ETH.MESH.00750766	ETH.MESH.00750769
11/21/2005	Process Qualification Completion Report Version 1	ETH.MESH.00752863	ETH.MESH.00752893
	RMR - TVT-S	ETH.MESH.00752921	ETH.MESH.00752925
	Risk Management Report Revision History for RMR-0000021	ETH.MESH.00752928	ETH.MESH.00752932
	TVT Secur Harm/Hazards Table	ETH.MESH.00752933	ETH.MESH.00752934
12/17/2008	Osman R email chain re 2008 Budget Spend	ETH.MESH.00772228	ETH.MESH.00772229
12/17/2008	Osman R email chain re Updated Fair Balance for TVT Brochure	ETH.MESH.00772231	ETH.MESH.00772232
	Presentation: Gynecare TVT Secur Project Overview PLT REview	ETH.MESH.00826057	ETH.MESH.00826067
4/12/2007	Thunder Meeting Minutes	ETH.MESH.00832555	ETH.MESH.00832556
1/22/2008	Thunger Meeting Minutes	ETH.MESH.00832562	ETH.MESH.00832564
	Arnaud, Robinson presentation: Characteristics of Synthetic Materials Used in Prolapse and Incontinence Surgery	ETH.MESH.00838428	ETH.MESH.00838469
8/31/2007	Robinson D email chain re Asking TVT Complication? - Fraying	ETH.MESH.00844331	ETH.MESH.00844335
8/31/2007	Robinson D email Chain re Asking TVT Complication? - Fraying	ETH.MESH.00844341	ETH.MESH.00844344
5/27/2008	Risk Benefit Analysis TVT-S	ETH.MESH.00853802	ETH.MESH.00853806
1/22/2004	Presentation: Sales Training Launch Meeting Gynecare TVT Obturator System	ETH.MESH.00857821	ETH.MESH.00857923
	Luscombe presentation: Top Ten Reasons to Pursue Gynecare TVT Obturator System	ETH.MESH.00857891	ETH.MESH.00857893

DOCUMENTS

	Internal Dan Smith memo – Gynecare board discussed risk of no clinical prior to launch, will proceed as no clinical needed	Eth.Mesh.00858080	
	Smith D Memo re Gynecare Board risk discussion before launch	ETH.MESH.00858080	ETH.MESH.00858081
06/??/03	Gynecare R&D Monthly Update - June	ETH.MESH.00858092	ETH.MESH.00858093
3/4/2003	Gynecare R&D Monthly Update - March	ETH.MESH.00858094	ETH.MESH.00858095
	Gynecare R&D Monthly Update -- May	ETH.MESH.00858096	ETH.MESH.00858097
6/3/2003	Mulberry Weekly Meeting Minutes for 06/03/2003	ETH.MESH.00858175	ETH.MESH.00858177
	London Brown Memo to Smith re Mechanical Cut vs Laser Cut Mesh Rationale	ETH.MESH.00858252	ETH.MESH.00858253
	Smith D Memo TVT Secur Lessons Learned Review	ETH.MESH.00858636	ETH.MESH.00858641
	Where the market is heading	ETH.MESH.00858891	ETH.MESH.00858891
6/1/2009	Smith D email chain re Sample medio TVTO	ETH.MESH.00860142	ETH.MESH.00860144
6/2/2003	Smith D email re My notes from the Thursday evening presentation 5/22/03 and Friday's surgery	ETH.MESH.00862727	ETH.MESH.00862728
2/27/2004	Email re: 2 TVT Complaints concerning allegedly brittle mesh	Eth.Mesh.00863391	Eth.Mesh.00863393
2/27/2004	Smith D email chain re 2 TVT Complaints concerning allegedly brittle mesh	ETH.MESH.00863391	ETH.MESH.00863393
3/9/2004	Emails re: Complaint TVTO	Eth.Mesh.00863405	Eth.Mesh.00863407
3/9/2004	Luscombe B email chain re Complaint TVT-O	ETH.MESH.00863405	ETH.MESH.00863407
7/24/2003	Smith D email chain re TOVT developments	ETH.MESH.00864101	ETH.MESH.00864102
8/15/2001	Luscombe B email chain re Aug 11 program	ETH.MESH.00864131	ETH.MESH.00864133
5/5/2004	Smith D email chain re TVT-O	ETH.MESH.00864407	ETH.MESH.00864408
9/8/2004	Smith D email chain re Ongoing TVT-O Action Items	ETH.MESH.00864490	ETH.MESH.00864492
9/14/2004	Smith D email chain re Ongoing TVT-O Action Items	ETH.MESH.00864493	ETH.MESH.00864496
3/2/2004	Email re: Reminder on BLUE mesh!	Eth.Mesh.00865322	Eth.Mesh.00865323
3/2/2004	Owens C email chain re Reminder on BLUE mesh	ETH.MESH.00865322	ETH.MESH.00865323
8/14/2007	Thunder meeting minutes	ETH.MESH.00869908	ETH.MESH.00869909
		ETH.MESH.00869977	
6/2/2006	Expert Meeting Minutes - Meshes for Pelvic Floor Repair	ETH.MESH.00870466	ETH.MESH.00870476
6/6/2006	Ethicon Expert Meeting Meshes for Pelvic Floor Repair	Eth.Mesh.00870466	
8/13/2006	London Brown, A email chainre LIGHTning clinical strategy	ETH.MESH.00870481	ETH.MESH.00870482
2/8/2006	Yale M email chain re MHRA request - TVT (change to dying process)	ETH.MESH.00874032	ETH.MESH.00874035
		ETH.MESH.00876900	
1/18/2008	Zaddem V email re 510(k) mesh data	ETH.MESH.00906445	ETH.MESH.00906445
4/13/2005	Sunoco, Inc MSDS	ETH.MESH.00918015	ETH.MESH.00918019

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	MSDS for Sunoco C4001 Polypropylene Homopolymer.	Eth.Mesh.00918015	
1/1/1970	St Hilaire P re Bidirectional Elasticity Statement	ETH.MESH.00922443	ETH.MESH.00922446
	Weisberg M Final Draft CER	ETH.MESH.00998286	ETH.MESH.00998291
12/13/2005	St. Hilaire email chain re Clinical Expert Report Laser Cut Mesh	ETH.MESH.00998292	ETH.MESH.00998293
6/22/2006	Gadot, Harel email re LCM - Launch Strategy EMEA	ETH.MESH.00998347	ETH.MESH.00998347
4/18/2006	Weisberg M and Robinson D CER	ETH.MESH.00998349	ETH.MESH.00998355
3/9/2007	Smith D email chain re Draft of latest "cookbook"" after Germany trip	ETH.MESH.01000323	ETH.MESH.01000329
6/4/2013	Professional Education Index	ETH.MESH.01000449	ETH.MESH.01000452
12/19/2006	Robinson D email chain re TVT-S Cookbooks	ETH.MESH.01000731	ETH.MESH.01000733
2/8/2005	Final Report Ethicon Study No S04/2-2-1 A 3 month -re-clinical trial to assess the fixation force of a new TVT (TVTx) in the sheep model	ETH.MESH.01037530	ETH.MESH.01037545
	TVT and TVT-O Risk Management Report Rev. 1	Eth.Mesh.01066916	Eth.Mesh.01066932
	TVT and TVT-O RMR Rev 1	ETH.MESH.01066916	ETH.MESH.01066932
	Smith, Lond Brown presentation: Gynecare TVT Secur	ETH.MESH.01150009	ETH.MESH.01150059
		ETH.MESH.01154031	
6/6/2001	Barbolt Memo to Ciarroca re Biocompatibility Risk Assessment for the TVT-L Device	ETH.MESH.01159961	ETH.MESH.01159962
1/16/2001	Dormier D email chain re Corporate Product Characterization December Monthly Report	ETH.MESH.01160507	ETH.MESH.01160518
	Marketing Brochure - Make Data and Safety Your Choice	ETH.MESH.01186068	ETH.MESH.01186072
1/7/2009	Kirkemo A email chain re My revised writeup of the DeLeval and Waltregny visit	ETH.MESH.01202101	ETH.MESH.01202103
1/7/2009	Kirkemo A email chain re My revised writeup of the DeLeval and Waltregny Visit	ETH.MESH.01202101	ETH.MESH.01202103
11/14/2008	Hinoul presentation: The future of surgical meshes: the industry's perspective	ETH.MESH.01203957	ETH.MESH.01203998
11/14/2008	Hinoul Austria Presentation: The future of surgical meshes: the industry's perspective	ETH.MESH.01203957	ETH.MESH.01203957
	TVT Abbrevo Risk Management Report Rev. 1	Eth.Mesh.01212090	Eth.Mesh.01212099
	TVT-Abbrevo RMR Rev 1	ETH.MESH.01212090	ETH.MESH.01212099
	Hutchinson Final Report An Exploratory 91-Day Tissue Reaction Study of Polypropylene-Based Surgical Mesh in Rats	ETH.MESH.01217925	ETH.MESH.01217959
	Revision History for dFMEA0000242	ETH.MESH.01218019	ETH.MESH.01218019
	TVT Laser Cut Mesh Risk Management Report Rev. 1	Eth.Mesh.01218099	Eth.Mesh.01218103
	TVT RMR Rev 1	ETH.MESH.01218099	ETH.MESH.01218103
4/5/2007	State of Knowledge in "mesh shrinkage"--What we know	Eth.Mesh.01218361	Eth.Mesh.01218367
4/5/2007	Spychaj K memo re Shrinking meshes	ETH.MESH.01218361	ETH.MESH.01218367
3/19/2003	Final Test Report - Prolene	ETH.MESH.01218446	ETH.MESH.01218449

DOCUMENTS

5/9/2006	Flatow J email chair re Particle loss on TVT	ETH.MESH.01219629	ETH.MESH.01219630
3/20/2006	CPC-2006-0014, Completion Report for the Design Verification of TVT Laser Cut Mesh Particle Loss at 50%Elongation	Eth.Mesh.01219984	
3/20/2006	Flatow Completion Report for Design Verification of TVT Laser Cut Mesh	ETH.MESH.01219984	ETH.MESH.01219994
10/14/2003	Kammerer G re Technical data on competitive meshes from Europe	ETH.MESH.01220710	ETH.MESH.01220711
5/4/2006	Kammerer G email re New Standards for Urethral Slings	ETH.MESH.01221024	ETH.MESH.01221025
3/9/2006	Kammerer G email chain re Elongation properties of LCM	ETH.MESH.01221618	ETH.MESH.01221619
3/7/2006	Weisberg, Robinson Clinical Expert Report	ETH.MESH.01221735	ETH.MESH.01221740
	Elongation Characteristics of Laser Cut Prolene Mesh for TVT	Eth.mesh.01222075	Eth.mesh.01222079
2/28/2003	Cirellli - Histological evaluation and Comparison of Mechanical Pull Out Strength of Prolene Mesh and Prolene Soft Mesh in a Rabbit Model	ETH.MESH.01222617	ETH.MESH.01222654
	Nilsson Podcase Transcript	ETH.MESH.01228079	ETH.MESH.01228084
2/5/2008	Robinson CER Gynecare Prolift+M	ETH.MESH.01259495	ETH.MESH.01259509
6/28/2002	Lawler T email re Polypropylene Mesh	ETH.MESH.01264260	ETH.MESH.01264260
2/17/2011	Zaddem V email re mesh pore size - tissue compliance and contraction	ETH.MESH.01264497	ETH.MESH.01264498
3/14/2008	Risk Management Report (Legacy) for TVT and TVT-O	Eth.Mesh.01265223	Eth.Mesh.01265239
	RMR TVT and TVT-O Rev 1	ETH.MESH.01265223	ETH.MESH.01265239
	TVT and TVT-O Risk Management Report Rev. 2	Eth.Mesh.01268264	Eth.Mesh.01268277
	RMR for TVT and TVT-O Revision History for RMR-0000044	ETH.MESH.01268264	ETH.MESH.01268277
	TVT Laser Cut Mesh Risk Management Report Rev. 2	Eth.Mesh.01310061	Eth.Mesh.01310065
	TVT Laser Cut RMR Rev 2	ETH.MESH.01310061	ETH.MESH.01310065
	TVT Laser Cut Mesh Risk Management Report Rev. 3	Eth.Mesh.01310476	Eth.Mesh.01310481
	TVT RMR Rev 3	ETH.MESH.01310476	ETH.MESH.01310481
		ETH.MESH.01316489	
5/14/2001	Target Sheet Design History: DH0263-DH0278	ETH.MESH.01316727	ETH.MESH.01316765
5/14/2001	Target Sheet Design History: DH0263-DH0278	ETH.MESH.01317508	ETH.MESH.01317613
4/25/2002	DDSA Re-Evaluation for TVT	ETH.MESH.01317510	ETH.MESH.01317514
7/12/2000	TVT-2 needles Introducer Revision 8	ETH.MESH.01317515	ETH.MESH.01317524
5/14/2001	TVT-O Design History Book 2 of 7	ETH.MESH.01317769	ETH.MESH.01318358
	TVT-O Design History Book 2 of 7	Eth.Mesh.01317769	
5/14/2001	Target Sheet DH1017-DH1019(bk5)	ETH.MESH.01318359	ETH.MESH.01318831
	TVT-O Design History Book 4 of 7	Eth.Mesh.01318359	
5/14/2001	TVT-O Design History Book 6 of 7	ETH.MESH.01318832	ETH.MESH.01319499
	TVT-O Design History Book 6 of 7	Eth.Mesh.01318832	
5/14/2001	TVT-O Design History Book 7 of 7	ETH.MESH.01319500	ETH.MESH.01320123

DOCUMENTS

	TVT-O Design History Book 7 of 7	Eth.Mesh.01319500	
6/18/2007	Volpe, Meier presentation: Exploratory Program "Thunder" A Material designed for pelvic floor	ETH.MESH.01405166	ETH.MESH.01405166
1/3/2009	Potential Failure Mode and Effects Analysis Chart Process FMEA	ETH.MESH.01407837	ETH.MESH.01407857
3/21/2006	Product Specification TVT-S Revision B	ETH.MESH.01410044	ETH.MESH.01410047
	Test Report No. B0086/02 Test for local effects after implantation	ETH.MESH.01424246	ETH.MESH.01424290
7/11/2001	91-day intramuscular tissue reaction study conducted in rats.	Eth.Mesh.01425079	ETH.MESH.01425113
2/27/2006	Design Validation Report TVTSDVLPRD2	ETH.MESH.01592178	ETH.MESH.01592188
	Ethicon Memo re: Prolene Pore Size	Eth.Mesh.01752532	
	Ethicon R&C Memo re Mesh design argumentation issues	ETH.MESH.01752532	ETH.MESH.01752535
	Clinical Expert Report ULTRAPRO	ETH.MESH.01760853	ETH.MESH.01760861
12/15/2006	Arnaud A email re TVT-S Cookbooks	ETH.MESH.01770534	ETH.MESH.01770534
	TVT-Secur: "Hammock" position - description for right-handed surgeon	ETH.MESH.01770535	ETH.MESH.01770540
	TVT-Secur: "U" Position - description for right-handed surgeon	ETH.MESH.01770541	ETH.MESH.01770546
12/20/2006	Robinson emai chainl re TVT-S Cookbooks	ETH.MESH.01784428	ETH.MESH.01784435
	LCM CER	Eth.mesh.01784823	Eth.mesh.01784828
1/17/2010	Hinoul, P email chain re +M relaxation	ETH.MESH.01785259	ETH.MESH.01785260
0/0/2010	Hinoul email reporting meeting with Klosterhalfen	Eth.Mesh.01785259	
8/17/2010	Clinical Expert Report TVT Abbrevo	ETH.MESH.01795909	ETH.MESH.01795929
	Abbrevo Clinical Expert Report	Eth.Mesh.01795909	
	Draft Smith presentation: The Mesh Story	ETH.MESH.01805985	ETH.MESH.01806002
4/25/2002	Test Report - Prolene	ETH.MESH.01808729	ETH.MESH.01808741
12/14/2004	Leibowitz B Memo re Comparison of Laser-Cut and Machine-Cut TVT Mesh to Meshes from Competitive Devices	ETH.MESH.01809080	ETH.MESH.01809081
12/14/2004	Leibowitz B Memo re Comparison of Laser-Cut and Machine-Cut TVT Mesh to Meshes from Competitive Devices (BE-2004-1641)	ETH.MESH.01809080	ETH.MESH.01809081
	London-Brown A Memto to Parisi, Mahar re VOC on new Laser Cut TVT Mesh	ETH.MESH.01809082	ETH.MESH.01809083
11/29/2004	Parisi P email re TVT Laser cut mesh business case	ETH.MESH.01811758	ETH.MESH.01811758
12/10/2004	Bell S email chain re VOC on Laser cut mesh	ETH.MESH.01811770	ETH.MESH.01811772
6/20/2003	Elbert K email chain re Design Control	ETH.MESH.01814371	ETH.MESH.01814372
	Work Instruction for New Product Design Control	ETH.MESH.01814384	ETH.MESH.01814400
8/17/2004	Burns J email chain re TVT-O Dr. Feagins case follow up	ETH.MESH.01815505	ETH.MESH.01815513
6/17/2003	Smith D email chain re Discussion 11th June 2003	ETH.MESH.01815611	ETH.MESH.01815613
	Spreadhseet mesh characeristis	ETH.MESH.01816988	ETH.MESH.01816989
5/9/2006	Mesh Development Timeline	Eth.Mesh.01816990	
??/??/06	Mesh development timeline	ETH.MESH.01816990	ETH.MESH.01816990

DOCUMENTS

7/31/2007	Thunder Meeting minutes	ETH.MESH.01819505	ETH.MESH.01819506
7/5/2009	Robinson Literature Review - Pelvic Organ Prolapse Repair Procedures	ETH.MESH.01819528	ETH.MESH.01819572
10/18/2006	Smith D email chain re TVT-Secur	ETH.MESH.01822361	ETH.MESH.01822363
3/25/2004	Zaddem V email chain re disclosure questions	ETH.MESH.01988643	ETH.MESH.01988644
	Test Method Applicability/Suitability Rev History for FM-0000020	ETH.MESH.01992234	ETH.MESH.01992237
2/16/2011	Biomechanical consideration for Pelvic floor mesh design	ETH.MESH.02010834	ETH.MESH.02010855
12/2/2004	Rousseau R email re umbilical hernia surgery sales contacts	ETH.MESH.02011199	ETH.MESH.02011199
2/23/2007	Ethicon Expert Meeting: Meshes for Pelvic Floor Repair brochure	ETH.MESH.02017152	ETH.MESH.02017158
03/??/01	Hellhammer B Meshes in Pelvic Floor Repair Findings from literature reivew and interviews with surgeons	ETH.MESH.02017169	ETH.MESH.02017190
		ETH.MESH.02017169	
	Biocompatability of Prosima components final draft insert into 510k	ETH.MESH.02020023	ETH.MESH.02020024
4/13/2005	Sunco C4001 Polypropylene Homopolymer MSDS	ETH.MESH.02026591	ETH.MESH.02026595
??/??/03	Marketing brochure Gynemesh PS A New Mesh for Pelvic Floor Repair Early Clinical Experience	ETH.MESH.02053629	ETH.MESH.02053632
		ETH.MESH.02053629	
5/21/2009	Protocol Study Title: A Phase 2 Study to Evaluate the Safety ad Efficiary of the Fibrin Pad Hemostatic Dressing in Trauma Patients Undergoing Re-Laprotomy after Initial Damages Control Surgery	ETH.MESH.02059212	ETH.MESH.02059232
6/22/2001	Scientific Advisory Panel on Pelvic Floor Repair Preliminary Minutes	ETH.MESH.02089392	ETH.MESH.02089399
8/8/2006	Holste Barbolt Mesh chara sign page	ETH.MESH.02091873	ETH.MESH.02091873
	Physician Post-Operative Questionnaire	ETH.MESH.02106803	ETH.MESH.02106803
6/18/2008	KOL Interview: Carl G. Nilsson	ETH.MESH.02126222	ETH.MESH.02126227
10/6/2008	Barbolt, T. Mechanisms of Cytotoxicity for TVT Polypropylene	Eth.Mesh.02134271	
	Memo to Rippy re Mechanisms of Cytotoxicity for TVT Polypropylene Mesh	ETH.MESH.02134271	ETH.MESH.02134273
5/26/2000	Corporate Product Characterization Product Safety Profile for PROLENE Mesh	Eth.Mesh.02134274	
5/26/2000	Product Safety Profile	ETH.MESH.02134274	ETH.MESH.02134279
12/5/2003	Biocompatibility Risk Assessment for the Gynecare TVT	Eth.Mesh.02134312	
12/5/2003	Memo re Biocompatibility Risk Assessment for the Gynecare TVT Obturator	ETH.MESH.02134312	ETH.MESH.02134314
	TVT Secur System Design Validation Report	ETH.MESH.02135955	ETH.MESH.02135968

DOCUMENTS

4/22/2009	Holste J email chain re Question on Moncryl absorption	ETH.MESH.02148431	ETH.MESH.02148432
06/??/09	Intermediate Report - Prolapse Mesh Explants 6/2009	ETH.MESH.02157879	ETH.MESH.02157880
3/26/2008	Robinson D email chain re UP	ETH.MESH.02170708	ETH.MESH.02170709
6/24/2003	Toddywala R email re Project Mulberry	ETH.MESH.02180737	ETH.MESH.02180737
3/29/2004	Memo from Jean de Leval, MD	Eth.Mesh.02180759	
3/29/2004	de Leval J memo	ETH.MESH.02180759	ETH.MESH.02180761
11/12/2004	Email re: Mesh Fraying: Dr. EBERHARD Fraying: DR. EBERHARD letter	Eth.Mesh.02180826	Eth.Mesh.02180827
11/12/2004	Menneret D email chain re Mesh Fraying: Dr. Eberhard letter	ETH.MESH.02180826	ETH.MESH.02180827
11/10/2004	Sibylle B Memo to Menneret D re TVT blue	ETH.MESH.02180828	ETH.MESH.02180830
10/18/2004	Translation of PD Doctor Eberhard's letter	ETH.MESH.02180833	ETH.MESH.02180833
4/22/2003	Burkley D email chain re Pore size request	ETH.MESH.02183533	ETH.MESH.02183536
4/3/2009	Rathore O email chain re Analytical characterization - Optimization of STructure	ETH.MESH.02184435	ETH.MESH.02184436
4/27/2010	Flint J email chain re surface area	ETH.MESH.02185004	ETH.MESH.02185004
2/16/2011	Biomechanical consideration for Pelvic floor mesh design	ETH.MESH.02185584	ETH.MESH.02185605
10/16/2007	Arnold, K email chain re LIghtning - Mesh Strength Design Requirement	ETH.MESH.02195798	ETH.MESH.02195799
2/5/2008	Robinson CER Gynecare Prolift +M	ETH.MESH.02198933	ETH.MESH.02198947
6/10/2008	Batke B email chain re Bisphenol A (BPA) - Question	ETH.MESH.02207388	ETH.MESH.02207389
	Spreadsheet re Mesh characteristics	ETH.MESH.02212840	ETH.MESH.02212842
08/??/10	Presentation: TOPA & SCION PA Alignment	ETH.MESH.02218268	ETH.MESH.02218292
	Presentation Script	ETH.MESH.02219162	ETH.MESH.02219164
	Rule 26 Expert Report of Howard Jordi, PhD in Carolyn Lewis case	ETH.MESH.02219202	ETH.MESH.02220048
	Meshes/Devices Chart	ETH.MESH.02227368	ETH.MESH.02227368
	Meshes/Devices	ETH.MESH.02227368	ETH.MESH.02227368
1/13/2011	TVT-O Marketing video	ETH.MESH.02229061	ETH.MESH.02229061
	Abbrevo marketing video	Eth.Mesh.02229061	
	2011 Article titled “An Anatomic Comparison of the Original Versus a Modified Inside-Out Transobturator Procedure.”	Eth.Mesh.02234752	
10/25/2010	Vellucci L email chain re Pelvic Floor Mesh	ETH.MESH.02252055	ETH.MESH.02252057
2/3/2003	Burkley D email chain re Athos: Analytical Testing	ETH.MESH.02268613	ETH.MESH.02268614
2/21/2003	Dion, D email re Prolene additives and exposure	ETH.MESH.02268618	ETH.MESH.02268618
1/23/2003	Prolene Resin Manufacturing Specifications Letter	Eth.Mesh.02268619	ETH.MESH.02268621
1/23/2003	Prolene Resin Manufacturing Specs 1.23.03	ETH.MESH.02268619	ETH.MESH.02268621
2/26/2004	Samon J email chain re mesh implants - user needs	ETH.MESH.02270823	ETH.MESH.02270825
		ETH.MESH.02283781	
1/13/2005	O'Bryan S email chain re IFU Prolift	ETH.MESH.02286052	ETH.MESH.02286053

DOCUMENTS

	Spreadsheet re matrix new material - improved mesh characteristics	ETH.MESH.02310498	ETH.MESH.02310498
	Landgreve S, Smith D, Trzewik J,Matrix - A powerful new tool in "Advanced Tissue Reconstruction:	ETH.MESH.02310501	ETH.MESH.02310501
10/21/2008	Pompilio S email re Information about FDA notification on use of mesh in pelvic surgery	ETH.MESH.02310653	ETH.MESH.02310657
	PPT Presentation titled "Tissue Reaction and Integration of Polypropylene-Based Surgical Mesh in Rats" by R.W. Hutchinson and Thomas Barbolt	ETH.MESH.02319001	
08/??/01	TVT IFU	ETH.MESH.02340306	ETH.MESH.02340369
	TVT IFU	ETH.MESH.02340331	ETH.MESH.02340335
2/11/2005	TVT IFU	ETH.MESH.02340471	ETH.MESH.02340503
10/13/2008	TVT IFU	ETH.MESH.02340504	ETH.MESH.02340567
12/16/2005	TVT-S IFU	ETH.MESH.02340568	ETH.MESH.02340755
3/7/2005	TVT-O IFU 03/07/20050-005/19-2005	ETH.MESH.02340756	ETH.MESH.02340828
	TVT-O IFU (3/7/2005-5/19/2005)	Eth.Mesh.02340756	
1/7/2004	TVT-O IFU (1/7/2004-3/4/2005)	ETH.MESH.02340829	ETH.MESH.02340901
	TVT-O IFU (1/7/2004-3/4/2005)	Eth.Mesh.02340829	
5/12/2010	TVT-O IFU (05/12/2012-present)	ETH.MESH.02340902	ETH.MESH.02340973
	TVT-O IFU (5/12/2010-present)	Eth.Mesh.02340902	
5/25/2005	TVT-O IFU (05/25/2005-04/29/2008)	ETH.MESH.02340974	ETH.MESH.02341046
	TVT-O IFU (5/25/2005-4/29/2008)	Eth.Mesh.02340974	
4/23/2008	TVT-O IFU (04/23/2008-05/07/2010)	ETH.MESH.02341047	ETH.MESH.02341118
	TVT-O IFU (4/23/2008-5/7/2010)	Eth.Mesh.02341047	
	Prosima IFU	ETH.MESH.02341407	ETH.MESH.02341410
4/23/2013	IFU Index and Production Bates Range Chart	ETH.MESH.02341954	ETH.MESH.02341954
4/25/2013	IFU Index	ETH.MESH.02342194	ETH.MESH.02342194
	No mesh is the best . . .	ETH.MESH.02588170	ETH.MESH.02588180
	Trzewik, Meier presentation: Exploratory Program "Thunder" A new material designed for pelvic floor	ETH.MESH.02588182	ETH.MESH.02588193
12/14/2010	ERM team meeting minutes	ETH.MESH.02588977	ETH.MESH.02588978
5/18/2011	PA Consulting Group Report: Investigating Mesh Erosion in Pelvic Floor Repair	ETH.MESH.02589032	ETH.MESH.02589079
11/24/2010	TVT Abbrevo PPT Presentation.	Eth.Mesh.02596794	
11/24/2010	TVT Abbrevo Dublin Meeting brochure	ETH.MESH.02596794	ETH.MESH.02596794
		ETH.MESH.02612883	
	Ultrasonic Slitting of PROLENE Mesh for TVT Feasibility Study	ETH.MESH.02614396	ETH.MESH.02614517
1/3/2012	Prosima 510(k) clearance letter	ETH.MESH.02658539	ETH.MESH.02658542
6/16/2008	Design Requirements Matrix Prolift+M /Lightning	ETH.MESH.02915783	ETH.MESH.02915797
	Study Notes	ETH.MESH.02992136	ETH.MESH.02992137
	Judi Gauld presentation: Evidence to Support Innovation	ETH.MESH.02995494	ETH.MESH.02995500

DOCUMENTS

8/25/2008	Draft - Presentation: T-Pro (Thunder) Pipeline Leadership Team (PLT) Stage Gate: Discovery Initiation	ETH.MESH.03021946	ETH.MESH.03021970
	Presentation: FDA REview R&D	ETH.MESH.03032928	ETH.MESH.03032944
2/16/2011	Holste email chain re Prosima +M clin strat	ETH.MESH.03146492	ETH.MESH.03146493
8/12/2007	Project plan Prosima M project lightning	ETH.MESH.03294572	ETH.MESH.03294581
5/1/2006	Kammerer G email chain re French Standard on TVT & Meshes (Comments required)	ETH.MESH.03358217	ETH.MESH.03358224
3/6/2006	Kammerer G Memo to Weisbert and Robinson re Elongation Characteristics of Laser Cut PROLENE Mesh for TVR	ETH.MESH.03358398	ETH.MESH.03358402
		ETH.MESH.03360387	
3/16/2004	Smith D email chain re TVTO training Carmel Ramage	ETH.MESH.03364540	ETH.MESH.03364544
??/??/09	TVT IFU	ETH.MESH.03427878	ETH.MESH.03427946
	Chart of pain associated with TVT-O.	Eth.Mesh.03454726	
10/12/2005	Holloway ltt Ethicon France re fraying	ETH.MESH.03535750	ETH.MESH.03535750
11/22/2005	Process Qualification Completion Report	ETH.MESH.03648795	ETH.MESH.03648810
	Revision History for FM-0000167	ETH.MESH.03652924	ETH.MESH.03652955
	Table re Raw data for force to achieve elongation	ETH.MESH.03658980	ETH.MESH.03658980
9/10/2009	Ng W email chain re August 2009 YTD Travel & Consulting spend	ETH.MESH.03699545	ETH.MESH.03699546
	Weisberg Clinical Expert Report Gynecare TVT Secur System	ETH.MESH.03714599	ETH.MESH.03714614
10/14/2011	Polypropylene Mesh for Pelvic Floor Repair - Focus on Mesh Exposure Road to Improvement - Bailhe	ETH.MESH.03719177	ETH.MESH.03719195
3/12/2012	Smith D email chain re tape position at rest	ETH.MESH.03731339	ETH.MESH.03731340
	Revision History (PR602-003)	ETH.MESH.03742571	ETH.MESH.03742597
5/10/2013	Bentley G email chain re Production of Policy before design 30(b)(6) deposition	ETH.MESH.03742864	ETH.MESH.03742865
	PA Consulting	ETH.MESH.03750903	ETH.MESH.03750950
	Spreadsheet product characteristics	ETH.MESH.03751168	ETH.MESH.03751175
	Table comparing meshes	ETH.MESH.03751168	ETH.MESH.03751168
5/18/2010	TVT Abbrevo Launch Planning Stage Gate PLT brochure	ETH.MESH.03753682	ETH.MESH.03753682
	Abbrevo Launch PPT Wanted to meet unmet demand of less persistent pain with Obturator	Eth.Mesh.03753682	
8/8/2003	Email re: Transient Leg Pain with MULBERRY	Eth.Mesh.03803462	
8/8/2003	Angelini L email chain re Transient Leg Pain with Mulberry	ETH.MESH.03803462	ETH.MESH.03803465
	Hellhammer Meshes in Pelvic Floor Repair - Findings from literature review and conversations/interviews with surgeons	ETH.MESH.03904451	ETH.MESH.03904480
6/6/2001	Emails re TVT recommendation from Dr. Alex Wang	Eth.Mesh.03905472	

DOCUMENTS

6/6/2001	Weisberg, M email chain re TVT recommendation from Dr. Alex Wang	ETH.MESH.03905472	ETH.MESH.03905472
9/18/2005	Weisberg M email chain re clinical expert report	ETH.MESH.03905619	ETH.MESH.03905621
10/14/2002	"Confidential - Trans-Obturator TVT - Procedure In-Out" by Axel Arnaud	Eth.Mesh.03907327	Eth.Mesh.03907330
10/17/2002	Arnaud Memo "Confidential Trans-Obturator TVT-Procedure In-Out"	ETH.MESH.03907327	ETH.MESH.03907330
5/1/2002	Document titled: "Second Generation TVT" by Axel Arnaud	Eth.Mesh.03907468	
5/1/2002	"Second Generation TVT" by Axel Arnaud	ETH.MESH.03907468	ETH.MESH.03907469
6/6/2003	LeTreguilly L email chain re TVT Serious complication	ETH.MESH.03907853	ETH.MESH.03907854
4/27/2005	Evans P email re Prolene v Polypropylene	ETH.MESH.03908707	ETH.MESH.03908708
8/21/2000	ARnaud A email chain re Pelvic floor repair Procedural Strategy	ETH.MESH.03909708	ETH.MESH.03909713
10/13/2002	Email re: Soft Prolene	Eth.Mesh.03910183	ETH.MESH.03910193
10/13/2002	Arnaud email chain re Soft Prolene	ETH.MESH.03910183	ETH.MESH.03910185
11/26/2002	Arnaud A email chain re Mini TVT - mesh adjustment	ETH.MESH.03910418	ETH.MESH.03910421
7/21/2004	Arnaud A email chain re TVT Erosion	ETH.MESH.03910799	ETH.MESH.03910800
5/25/2003	Arnaud A email re Follow up Mulberry	ETH.MESH.03910890	ETH.MESH.03910892
2/20/2003	Email re: TVT complications (an Prof. Hausler)	Eth.Mesh.03911107	Eth.Mesh.03911108
2/20/2003	Arnaud A email chain re TVT complications (an Prof. Häusler)	ETH.MESH.03911107	ETH.MESH.03911108
2/20/2003	Arnaud, A email chain re TVT complication (an Prof. Hausler)	ETH.MESH.03911107	ETH.MESH.03911108
8/14/2003	Arnaud A email chain re Transient Leg Pain with Mulberry	ETH.MESH.03911390	ETH.MESH.03911394
1/31/2006	Email re: TVT-TVT-O Specifications	Eth.Mesh.03911712	
1/31/2006	Arnaud A email chain re TVT - TVT-O Specifications	ETH.MESH.03911712	ETH.MESH.03911715
1/8/2007	Arnaud A eail re TVT Cookbooks	ETH.MESH.03912639	ETH.MESH.03912639
	Draft re TVT-S IFU	ETH.MESH.03912647	ETH.MESH.03912651
4/14/2005	Toddywala, R email chain re Ultrapro	ETH.MESH.03915567	ETH.MESH.03915572
4/12/2005	Kammerer, G email chain re Ultrapro	ETH.MESH.03915588	ETH.MESH.03915590
4/15/2008	04/15/2008 Notes	ETH.MESH.03916716	ETH.MESH.03916727
1/7/2009	Hinoul P email chain re My revised writeup of the DeLeval and Waltregny visit	ETH.MESH.03916905	ETH.MESH.03916913
11/28/1999	Bianchi R email chain re TVT event	ETH.MESH.03917309	ETH.MESH.03917312
10/18/2002	Email re Gynemesh	ETH.MESH.03918067	ETH.MESH.03918068
3/26/2003	Arnaud A email re Mulberry	ETH.MESH.03919404	ETH.MESH.03919405
12/19/2006	Robinson D email chain re TVT Secur	ETH.MESH.03921499	ETH.MESH.03921500
12/5/2006	Smith D email chain re TVT-SECUR follow up on conference call	ETH.MESH.03921580	ETH.MESH.03921583
11/30/2006	Gotter R email re The more procedures the more problems	ETH.MESH.03921612	ETH.MESH.03921612
10/3/2007	Beveridge A email re AMS mini Arc	ETH.MESH.03922261	ETH.MESH.03922261

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6/6/2007	Beveridge A email chain re TVT Secure & Nice	ETH.MESH.03922405	ETH.MESH.03922406
1/16/2007	Robinson D email chain re TVT Secur procedural steps	ETH.MESH.03922950	ETH.MESH.03922951
1/16/2007	Buchon X email chain re French data on TVT Secur	ETH.MESH.03922953	ETH.MESH.03922953
1/10/2007	Robinson D email chain re Report from Austria	ETH.MESH.03922966	ETH.MESH.03922967
6/6/2000	Hellhammer B - Meshes in Pelvic Floor Repair Findings from literature review and conversations/interviews with surgeons	ETH.MESH.03924557	ETH.MESH.03924586
		ETH.MESH.03924557	
	Meeting Notes	ETH.MESH.03926030	ETH.MESH.03926031
1/16/2007	"Confidential: History of TVT-O" by Axel Arnaud	Eth.Mesh.03932909	Eth.Mesh.03932911
	History of TVT-O	ETH.MESH.03932909	ETH.MESH.03932911
	The history of TVT	ETH.MESH.03932912	ETH.MESH.03932914
2/20/2006	Buchon X email chain re Pr Cosson	ETH.MESH.03938897	ETH.MESH.03938898
4/3/2012	deLeval J email re Alerte TVT Abbrevo	ETH.MESH.03941617	ETH.MESH.03941618
4/3/2012	Hinoul P email chain re Alerte TVT Abbrevo	ETH.MESH.03941621	ETH.MESH.03941622
9/13/2006	Prolene Resin Testing	ETH.MESH.03949361	ETH.MESH.03949365
3/1/2012	Batke B email chain re AGES Pelvic Floor Conference - Gala Dinner Invitation	ETH.MESH.04015102	ETH.MESH.04015104
4/13/2005	Holste, J email chain re Ultrapro	ETH.MESH.04020134	ETH.MESH.04020137
1/13/2005	Report - Analysis of Competitors meshes: Dynamesh, Dynamesh Light, Dynamesh IPOM	ETH.MESH.04036976	ETH.MESH.04036981
	Innovations in Mesh Development Boris Batke	ETH.MESH.04037600	ETH.MESH.04037600
2/29/2012	Jamiolkowski D email chair re Your Professional Opinion	ETH.MESH.04038180	ETH.MESH.04038181
10/??/00	TVT Update Success & Complications - Bernard Jacquetin	ETH.MESH.04044797	ETH.MESH.04044800
6/18/2008	Carl G. Nilsson Interview	ETH.MESH.04048515	ETH.MESH.04048520
6/25/2008	KOL Interview: Carl G. Nilsson	ETH.MESH.04048515	ETH.MESH.04048515
05/26/????	Michele Meschia Presentation: The evolution of slings for SUI	ETH.MESH.04058175	ETH.MESH.04058209
	5/26-27 PPT Presentation titled “The Evolution of Slings for SUI.”	Eth.Mesh.04058175	
8/4/2009	Fujihara M email re SUI & PFR New Competitor Identified in Brazil	ETH.MESH.04066979	ETH.MESH.04066980
2/2/2009	Meeting Agenda "AE and complication of the lsings	ETH.MESH.04081189	ETH.MESH.04081190
2/9/2009	Meeting Agenda by Meng Chen re "AE and complication of the slings"	Eth.Mesh.04081189	Eth.Mesh.04081190
1/29/2009	Email re: TVT IFUs on tape extrusion, exposure and erosions	Eth.Mesh.04093125	
1/29/2009	Chen M email re TVT IFUs on tape extrusion, exposure and erosion	ETH.MESH.04093125	ETH.MESH.04093125
1/9/2007	Gadot H email chain re Report from Austria	ETH.MESH.04204341	ETH.MESH.04204342
12/??/06	Womens Health - Monthly Report December 06	ETH.MESH.04204343	ETH.MESH.04204343
	PDP Design Control Revision History for PR800-011	ETH.MESH.04316544	ETH.MESH.04316562

DOCUMENTS

3/21/2006	Process Specificagtion Gynecare TVT Secure	ETH.MESH.04385192	ETH.MESH.04385197
7/19/1996	Product Safety Profile - Prolene	ETH.MESH.04447134	ETH.MESH.04447142
3/5/2012	CDMA Meeting Minutes - 2012	ETH.MESH.04548236	ETH.MESH.04548242
3/20/2012	Hinoul P email chain re Polypropylene Mesh	ETH.MESH.04937874	ETH.MESH.04937876
4/2/2012	Hinoul P email chain re Prof de Leval - TVT Abbrevo	ETH.MESH.04938298	ETH.MESH.04938299
2/28/2006	Corporate Product Characterization Plan for Gynecare TVT-S	ETH.MESH.04939027	ETH.MESH.04939035
7/18/2005	Corporate Product Characterization Plan for Gynecare TVT S	ETH.MESH.04939148	ETH.MESH.04939157
7/16/2010	Holste, Jophnson Memo to Leslie Young re Preclinical Efficacy Assessment for Ethicon Gynecare Gynemesh	ETH.MESH.04940233	ETH.MESH.04940233
	Holste presentation: Lightweight Mesh Developments	ETH.MESH.04941016	ETH.MESH.04941049
4/18/2005	Klosterhalfen B email re Ultrapro vs Prolene Soft Mesh	ETH.MESH.04945496	ETH.MESH.04945496
2/3/2012	Email thread re: A few things.	Eth.Mesh.05107016	
2/3/2012	Cheng, K email chain re a few things	ETH.MESH.05107016	ETH.MESH.05107017
	Spreadsheet of Ethicon product positioning for various products.	Eth.Mesh.05109369	
	Spreadsheet re product positioning	ETH.MESH.05109369	ETH.MESH.05109398
1/20/2010	Holste email chain re Tissue reaction ULTRAPRO	ETH.MESH.05127423	ETH.MESH.05127430
11/7/2005	Patire-Singer W email chain re TVT Records	ETH.MESH.05220458	ETH.MESH.05220464
4/7/2006	TVT IFU	ETH.MESH.05222673	ETH.MESH.05222705
7/1/2010	TVT Abbrevo 510(k) Clearance and Application	Eth.Mesh.05224295	
7/1/2010	TVT Abbrevo 510(k) Clearance and Application	ETH.MESH.05224295	ETH.MESH.05224391
9/8/2000	TVT-IFU	ETH.MESH.05225354	ETH.MESH.05225385
	TVT IFU	ETH.MESH.05225380	ETH.MESH.05225384
	Meier presentation: Mesh Properties - How important are they?	ETH.MESH.05237872	ETH.MESH.05237910
4/8/2009	Hinoul email chain re Tensile Properties of POP Mesh	ETH.MESH.05238373	ETH.MESH.05238374
4/9/2009	Jones, S email re Tensile Properties of POP Mesh	ETH.MESH.05238382	ETH.MESH.05238384
	Article on pp change in sheep model	ETH.MESH.05240144	ETH.MESH.05240144
	Presentation Wissenschaftliche Grundlagen adn klinsche Evidenz von Netz-Implantaten	ETH.MESH.05243697	ETH.MESH.05243704
12/21/2004	Holste email chain re TVT Next generation Questions	ETH.MESH.05245392	ETH.MESH.05245397
1/3/2006	Smith D email chain re REsults of TVTx prelinical trial	ETH.MESH.05246116	ETH.MESH.05246122
3/10/2005	Next Generation Mesh Discussion - Agenda	ETH.MESH.05246527	ETH.MESH.05246528
6/16/1999	28-day intramuscular tissue reaction study of TVT Mesh conducted in rats.	Eth.Mesh.05315240	ETH.MESH.05215295
1/8/2014	Deposition Subject Matter table	ETH.MESH.05315240	ETH.MESH.05315279
11/7/2002	Lab Notebook Histology Processing and Tissue Inventory Record	ETH.MESH.05316755	ETH.MESH.05316755

DOCUMENTS

11/6/2011	Miller D email chain re Prolift professional education	ETH.MESH.05337217	ETH.MESH.05337220
	Operating Procedure for Failure Modes and Effects Analsis	ETH.MESH.05432198	ETH.MESH.05432224
	Applied Science & Technology Performance Evaluation Abstract Biaxial testing of two commonly used Ethicon meshes	ETH.MESH.05442973	ETH.MESH.05442975
	Operating Procedure for Optical Evaluation to Determine Porosity of Mesh Samples Using the Nikon Stereomicroscope and Image-Pro Plus Image Analysis System	ETH.MESH.05443059	ETH.MESH.05443064
	Temocin - Pore Size Measurement of Surgical Mesh Products	ETH.MESH.05443077	ETH.MESH.05443085
3/13/2006	Holste J email chair re Mesh and Tissue Contraction in Animal	ETH.MESH.05446127	ETH.MESH.05446128
7/6/2007	Email thread re: How Inert is polypropylene?	Eth.Mesh.05447475	
7/6/2007	Engel D email chain re How inert is polypropylene?	ETH.MESH.05447475	ETH.MESH.05447476
	SEM Images for Ten Year PROLENE Study	Eth.Mesh.05453719	ETH,MESH.05453727
10/15/1992	Seven Year Data for Ten Year Prolene Study	ETH.MESH.05453719	ETH.MESH.05453727
8/1/2006	Trzweik J email chain re Fotos cadevar lab	ETH.MESH.05454207	ETH.MESH.05454214
1/18/2003	Ethicon Surgeon Panel Meeting Agenda, Notes	ETH.MESH.05455878	ETH.MESH.05455898
??/??/06	2006 Johnson Medal Nomination Ultrapro Loghtweight mesh product line	ETH.MESH.05457602	ETH.MESH.05457609
8/20/2012	Vellucci, ltr re Ethicon ceases to commenrcialize prosima	ETH.MESH.05467804	ETH.MESH.05467804
4/13/2005	Barbolt, T email chain re Ultrapro	ETH.MESH.05469908	ETH.MESH.05469912
11/??/08	Batke presentation: Ultrapro Plug Tokyo	ETH.MESH.05478745	ETH.MESH.05478780
10/??/03	Lightweight Mesh Value Proposition	ETH.MESH.05479410	ETH.MESH.05479410
11/10/2004	Presentation by Boris Batke (Ethicon R&D): The (clinical) argument of lightweight mesh in abdominal surgery	Eth.Mesh.05479411	
11/10/2004	PPT Presentation by Boris Batke: “The (Clinical Argument of Lightweight Mesh in Abdominal Surgery.”	Eth.Mesh.05479411	
11/10/2004	Presentation by Boris Batke: The (clinical) argument of lightweight mesh in abdominal surgery	ETH.MESH.05479411	ETH.MESH.05479411
	TVT and TVT-O RMR Rev 2	ETH.MESH.05479411	ETH.MESH.05479424
5/30/2011	Spreadsheet listing microporous, medium and macroporous meshes	Eth.Mesh.05479535	
	Product Spreadsheet	ETH.MESH.05479535	ETH.MESH.05479535
3/1/2011	Presentation: ETHICON Polypropylene Mesh Technology	Eth.Mesh.05479717	
03/??/11	Boris Batke presentation: ETHICON Polypropylene Mesh Technology	ETH.MESH.05479717	ETH.MESH.05479717
10/2/2003	Ultrapro Mesh Pricing Committee Presentation	ETH.MESH.05483362	ETH.MESH.05483362

DOCUMENTS

12/1/2007	Sponsored Research Contract The Curators of the University of Missouri	ETH.MESH.05489861	ETH.MESH.05489867
	Scientific Sgtatement Helhammer, Kohler, Holste, Shrinking Meshes?	ETH.MESH.05495419	ETH.MESH.05495422
2/27/2006	Design Requirements Matrix	ETH.MESH.05502894	ETH.MESH.05502928
	Clinical Infection Risk Assessment for Bynecare TVT Universal	ETH.MESH.05505944	ETH.MESH.05505946
12/19/2006	Smith D email chain re TVT-S Cookbooks	ETH.MESH.05519476	ETH.MESH.05519481
	RMR TVT Secur	ETH.MESH.05534013	ETH.MESH.05534017
11/1/2004	Smith D email chain re Update from Oct 27 cadaver lab	ETH.MESH.05548122	ETH.MESH.05548123
11/1/2004	Smith D email re Update from Oct 27 cadaver lab	ETH.MESH.05548122	ETH.MESH.05548123
4/29/2005	Komamycky P email chain re Bio compatibility samples	ETH.MESH.05549096	ETH.MESH.05549100
3/11/2005	Holste J email chain re Infection resk implantation TVT U	ETH.MESH.05549189	ETH.MESH.05549191
4/29/2005	Email re: Biocompatibility samples	Eth.Mesh.05549696	Eth.Mesh.05549700
4/7/2005	Gynecare Detail Drawings	ETH.MESH.05554367	ETH.MESH.05554371
4/4/2011	Vellucci, L email re coupld of things	ETH.MESH.05572810	ETH.MESH.05572810
2/28/2005	Batke B email chain re UltraPro sizing	ETH.MESH.05585063	ETH.MESH.05585066
7/9/2007	Wohlert S email chain re How inert is polypropylene?	ETH.MESH.05588123	ETH.MESH.05588126
8/27/2008	e-mail from Barbara Schudt to Dr. K. Junge re Ductus deferens Stdue	ETH.MESH.05588132	ETH.MESH.05588135
4/23/2001	Hellhammer B email chain re Vypro Pelvic Floor Repair PD 00/3	ETH.MESH.05642489	ETH.MESH.05642491
		eth.mesh.05642725	
	Pelvic Floor Repair -- Surgeon's Feed-back on Mesh Concept	ETH.MESH.05644163	ETH.MESH.05644171
5/8/2011	PA Consulting Group Report: Investigating Mesh Erosion in Pelvic Floor Repair	ETH.MESH.05701011	ETH.MESH.05701058
5/18/2011	PA Consulting Presentation: “Investigating Mesh Erosion in Pelvic Floor Repair.”	Eth.Mesh.05701011	
6/21/2011	Schmitt K email chain re Classification of Meshes - UPDATE	ETH.MESH.05718101	ETH.MESH.05718108
8/21/1973	28-day tissue reaction study conducted in rabbits.	ETH.MESH.0575607	ETH.MESH.0575613
1/16/2011	Presentation by Boris Batke	Eth.Mesh.05916450	
	Boris Batke Presentation: Chronic Pain Prevention/future--Bioengineer's point of view	ETH.MESH.05916450	ETH.MESH.05916450
	Presentation: Solving the Device Design Puzzle	ETH.MESH.05918082	ETH.MESH.05918116
5/4/2004	Schiaparelli J email re Marlex Experience	ETH.MESH.05918776	ETH.MESH.05918776
4/17/2003	Batke B email re Literature list Lightweight Meshes	ETH.MESH.05920530	ETH.MESH.05920530
7/20/2007	Email re: Defining light weight mesh	Eth.Mesh.05920616	Eth.Mesh.05920617
7/20/2007	Chomiak M email re Defining light weight mesh	ETH.MESH.05920616	ETH.MESH.05920617
2/12/2008	Koehler P email chain re Dr. Schumpelick	ETH.MESH.05920618	ETH.MESH.05920621
11/15/1999	Asset Purchase Agreement	ETH.MESH.05972834	ETH.MESH.05972866

DOCUMENTS

4/2/2012	Hinoul P email chain re Alerte TVT Abbrevo	ETH.MESH.05998811	ETH.MESH.05998812
5/10/2012	Hinoul P email chain re Alerte TVT Abbrevo	ETH.MESH.05998835	ETH.MESH.05998836
4/2/2006	Mahar K email chain re Laser Cut Mesh Positioning	ETH.MESH.06040171	ETH.MESH.06040173
1/16/2004	Smith D email re Dedications	ETH.MESH.06164409	ETH.MESH.06164410
??/??/10	R&D Co-Op Welcome Guide Spring 2010	ETH.MESH.06260647	ETH.MESH.06260671
8/26/2011	Karl J email chain re Braskem. . . A LIttle History	ETH.MESH.06261965	ETH.MESH.06261967
07/??/1995	Prolene Mesh Polypropylene Technical File	ETH.MESH.06398793	ETH.MESH.06398932
7/0/1995	PROLENE Technical File.	Eth.Mesh.06398827	
		ETH.MESH.06401339	
5/5/2005	Seppa K Memo re Performance Evaluation of TVT U Prolene Mesh: Mechanical Cut versus Laser Cut STudy (LIMS#BE-2005-1920) Version 3	ETH.MESH.06696367	ETH.MESH.06696379
	Performance Evaluation Technical Report	Eth.mesh.06696367	Eth.mesh.06696379
	Design FMEA: TVT Laser Cut Mesh Prljject spreadsheet	ETH.MESH.06696593	ETH.MESH.06696598
8/27/2008	CE Mark Technical File PMH-2008-01	ETH.MESH.06851860	ETH.MESH.06852464
	Presentation: TVT Obturator System	ETH.MESH.06856958	ETH.MESH.06856981
	Presentation: TVT-Bridge Retaining Leadership	ETH.MESH.06857406	ETH.MESH.06857417
1/29/2009	Smith D email chain re TVT-O resin Minute Jan 31th	ETH.MESH.06858146	ETH.MESH.06858147
	Test method for the Thickness of Mesh Revision Hisitory TM403-145	ETH.MESH.06858314	ETH.MESH.06858318
	Dodd presentation: TVT: Instights into the Making of a Revolution	ETH.MESH.06859904	ETH.MESH.06859931
8/8/2007	Hocknell J email chain re Adventures with TVT Secur	ETH.MESH.06861426	ETH.MESH.06861429
??/??/07	Presentation Competitive Produce Update	ETH.MESH.06861473	ETH.MESH.06861549
04/??/08	Presentation: Matrix Material A powerfu new tool in Advanced Tissue Reconstruction	ETH.MESH.06867612	ETH.MESH.06867630
1/16/2007	Juraschek R email chain re shrinkage review	ETH.MESH.06868377	ETH.MESH.06868382
8/18/2004	Human Cadaver Wetlab Report/Results Draft	ETH.MESH.06869750	ETH.MESH.06869753
2/14/2003	Due Diligence Growth Opportunity Outline re Project Mulberry Next generation TVT	ETH.MESH.06873447	ETH.MESH.06873458
0/0/2003	Due Diligence Memo	Eth.Mesh.06873447	
8/17/2004	Burns J email chain re TVT-O	ETH.MESH.06881576	ETH.MESH.06881580
6/22/2004	Burns J email re Gynecare TVT Obturator Global Launch Update - Issue 4	ETH.MESH.06881589	ETH.MESH.06881591
8/18/2004	Mahar K email re Dr. Jensen Follow UP	ETH.MESH.06884516	ETH.MESH.06884517
9/8/2004	Campbell S email chain re Ongoing TVT-O Action Items	ETH.MESH.06884726	ETH.MESH.06884727
2/19/2004	Smith D email re TVT-O recognition Submission	ETH.MESH.06892171	ETH.MESH.06892172
	Presentation: Evaluation of UltraPro Meshes	ETH.MESH.06893952	ETH.MESH.06893961
9/13/2010	CRS for TVT-O	ETH.MESH.06917699.	ETH.MESH.06917704.
11/10/2009	Lanza J email chain re Preread for Web Conference	ETH.MESH.06921060	ETH.MESH.06921077

DOCUMENTS

9/10/2010	TVTO-PA Clinical Strategy	ETH.MESH.06923868	ETH.MESH.06923871
4/7/2004	Pelekis M Memo re Risk Assessment for Laser Cutting of D'Art GynemeshPS Impalnts	ETH.MESH.07190442	ETH.MESH.07190446
1/20/2011	PA Consulting Group Mesh Erosion Interview - Surgeon meeting minutes	ETH.MESH.07192012	ETH.MESH.07192014
11/1/2010	JOe Robinson and Greg Berman Richter report re Investigation into mesh erosion in pelvic floor repair	ETH.MESH.07192033	ETH.MESH.07192041
2/17/2011	Meier P email re sales reps in Uk	ETH.MESH.07192242	ETH.MESH.07192242
1/18/2011	PA Consulting Group Mesh Erosion Interview—Pathology	Eth.Mesh.07192412	
1/18/2011	PA Consulting Group Mesh Erosion Interview Memo	ETH.MESH.07192412	ETH.MESH.07192414
5/18/2011	Hinoul email chain re Forces in the pelvic floor	ETH.MESH.07192872	ETH.MESH.07192872
6/22/2011	Investigating Mesh Erosion in Pelvic Repair	ETH.MESH.07192929	ETH.MESH.07192929
	PA Consulting	ETH.MESH.07192929	ETH.MESH.07192929
2/9/2011	Vailhe C email re You have been selected - Forces on the pelvic floor - challenge to determine	ETH.MESH.07197998	ETH.MESH.07197998
3/31/2011	Vailhe C email chain re Thanks & pictures	ETH.MESH.07198250	ETH.MESH.07198250
7/21/2011	Vailhe, C email chain re Mesh erosion report	ETH.MESH.07198825	ETH.MESH.07198828
1/16/2012	Veilhe C email re Biomechanics of the pelvic floor	ETH.MESH.07200224	ETH.MESH.07200224
2/1/2012	Vailhe C email re Exposure Position Norderstedt 2012.pptx	ETH.MESH.07200381	ETH.MESH.07200381
2/2/2012	Presentation: Mesh Exposure Ethicon Position	ETH.MESH.07200382	ETH.MESH.07200410
3/12/2012	Email re: Response to email from Clare Huntington 26 January 2012 regarding publication by Clave et al., Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants, Int. Urogynecol J (2010 21:261-270	Eth.Mesh.07205369	Eth.Mesh.07205370
3/12/2012	Savidge, et al response to email from Huntington re Clave' publication	ETH.MESH.07205369	ETH.MESH.07205370
3/6/2012	Response to email from Clare Huntington 26 January 2012 with attached publication: Polpropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants", Int Urgynecol J (2010) 21:261-270	ETH.MESH.07212397	ETH.MESH.07212398
	510(k) Premarket Notification - Prosima	ETH.MESH.07215395	ETH.MESH.07215575
3/1/2012	Email re: Polypropylene mesh - study of 100 explants	Eth.Mesh.07226377	Eth.Mesh.07226379
3/1/2012	Vellucci, L email chain re Polypropylene Mesh	ETH.MESH.07226377	ETH.MESH.07226379
3/7/2012	Jaiolkowski D email chain re Inforation on Prolene Suture and Prolene Mesh	ETH.MESH.07226404	ETH.MESH.07226405
5/13/2012	de Leval J email chain re Alerte TVT Abbrevo	ETH.MESH.07318311	ETH.MESH.07318313
2/23/2009	Zipfel R email chain re Ultrapro mesh info	ETH.MESH.07383730	ETH.MESH.07383731
0/0/2009	Email to Pramudji from Ethicon employee Robert Zipfel	Eth.Mesh.07383730	

DOCUMENTS

		ETH.MESH.07429428	
3/6/2012	Response to MHRA inquiry regarding inertness of polypropylene mesh	Eth.Mesh.07455220	
	Literature Summary	ETH.MESH.07465373	ETH.MESH.07465383
11/7/2001	Memo re Biocompatibility Risk Assessment for TVT-AA-Revised	ETH.MESH.07469275	ETH.MESH.07469281
8/19/1997	Corporate Product Characterization Product Safety Profile	Eth.Mesh.07469425	
8/19/1997	Product Safety Profile	ETH.MESH.07469425	ETH.MESH.07469432
	Biocompatability risk assessmetn - Prosima pelvic floor repair system -Mint	ETH.MESH.07506983	ETH.MESH.07506985
10/15/1992	Seven Year Data for Ten Year Prolene Study: ERF 85-219	ETH.MESH.07690752	ETH.MESH.07690788
10/15/1992	Seven Year Data for Ten Year PROLENE Study (and SEM images)	Eth.Mesh.07690752	ETH.MESH.07690788
	Annotated Notes	ETH.MESH.07726805	ETH.MESH.07726817
11/28/2005	Response to FDA Request for Add'l Information	ETH.MESH.07876820	ETH.MESH.07876925
		eth.mesh.07902279	
	Ethicon PPT Presentation titled “Scion PA Commercial Strategy.” Notes that Abbrevo is “less mesh, less pain.”	Eth.Mesh.07903520	
	Presentation: Sicon PA Commercial Strategy	ETH.MESH.07903520	ETH.MESH.07903520
6/30/2011	Affeld, T email chain re PS vs +M	ETH.MESH.07903682	ETH.MESH.07903683
12/9/2010	Irvin, M 12/08/2010 Post Call Notes	ETH.MESH.08041930	ETH.MESH.08041931
12/12/2006	Spychaj - State of the knowledge in "mesh shrinkage" -- What do we Know?	ETH.MESH.08168728	ETH.MESH.08168733
10/1/1997	Barbolt Memo to Robertson re Biocompatibility Risk Assessment for Proleen Polypropylene Mesh	ETH.MESH.08218336	ETH.MESH.08218336
10/1/1997	Barbolt memo to Robertson re Biocompatibility Risk Assessment for PROLENE Polypropylene Mesh	ETH.MESH.08218337	ETH.MESH.08218351
6/27/2013	Ex T-722 MItchell - Clinical Expert Report Gynecare Prolift +M	ETH.MESH.08315779	ETH.MESH.08315810
		ETH.MESH.08315779	
8/26/2011	Email thread re: Mini-slings vs. Standard Midurethral Slings!!	Eth.Mesh.08335798	
8/26/2011	Stewart, E email chain re Mini-slings vs Standard Midurethral Slings	ETH.MESH.08335798	ETH.MESH.08335799
5/1/2008	Ward J and Muench T Technical memo Project NUVANCE Risk Assessment on Implant Cross Over	ETH.MESH.08385338	ETH.MESH.08385342
	PR602-003 version 5 - Work Instructions for Device Design Risk Management	ETH.MESH.08438961	ETH.MESH.08438985
3/4/2008	Ciarrocca 2007 Performance and Development Plan Summary for Daniel Smith	ETH.MESH.08474542	ETH.MESH.08474546
3/8/2009	Mauge Yeard End Performance Summary	ETH.MESH.08474547	ETH.MESH.08474554
1/25/2010	Decosta 2009 Performance and Development Plan Summary for Daniel Smith	ETH.MESH.08474555	ETH.MESH.08474561

DOCUMENTS

1/8/2011	Decosta 2010 Performan and Development Plan Summary for Daniel Smith	ETH.MESH.08474562	ETH.MESH.08474569
1/20/2012	Decosta 2011 Performance and Development Plan Summary for Daniel Smith	ETH.MESH.08474570	ETH.MESH.08474577
10/17/1997	Eriksson Clinical Report - Scandinavian Multicenter Study of the Tension Free Vaginal Tape Procedure	ETH.MESH.08476335	ETH.MESH.08476342
	Revision Hx for PR800-011 Version 7	ETH.MESH.08477464	ETH.MESH.08477481
11/9/2010	e-mail from David Krause to Peter Cecchini, November 10, 2010	ETH.MESH.08516133	ETH.MESH.08516134
1/9/2012	Vailhe C email chain re Mes Exposure - Ethicon Position - Short List	ETH.MESH.08579092	ETH.MESH.08579093
	RMR - LCM Revision 2	ETH.MESH.08792102	ETH.MESH.08792106
7/29/2008	Kadadkia R email chain re TVT LCM - launch delay due to OQ failure	ETH.MESH.09004550	ETH.MESH.09004553
	Elongation test data	ETH.MESH.09004554	ETH.MESH.09004554
	Elongation test data - delayed launch	ETH.MESH.09004555	ETH.MESH.09004555
10/12/2006	Savidge, S email chain re 510k Mint tests pending	ETH.MESH.09052531	ETH.MESH.09052534
10/11/2010	Destefano C email re CR approved TVT-Abbrevo Clinical Data Review Flashcard	ETH.MESH.09161482	ETH.MESH.09161482
	Abbrevo marketing documents	Eth.Mesh.09161482 Eth.Mesh.11434367 Eth.Mesh.11434264	
	Abbrevo marketing video - script	Eth.Mesh.09170211	
	Abbrevo marketing video script	ETH.MESH.09170211	ETH.MESH.09170213
11/11/1998	Rousseau R Memo re Meeting Minutes of Project Planning Meeting	ETH.MESH.09264884	ETH.MESH.09264885
8/17/1998	Rousseau Memo to Lessig re Prolene Mesh Re-Design Project	ETH.MESH.09264945	ETH.MESH.09264946
6/23/1998	Ellington L email re Prolene Mesh for TVT	ETH.MESH.09266657	ETH.MESH.09266658
11/4/2005	Rousseau, R email chain re Gynemesh PS w/Monocryl	ETH.MESH.09268506	ETH.MESH.09268508
9/13/1999	E-Mail discussing generations of mesh	Eth.Mesh.09275875	
9/13/1999	Rousseau R email re samples of Prolene Mesh	ETH.MESH.09275875	ETH.MESH.09275876
	Prolene Mesh Improvement Project	ETH.MESH.09279097	ETH.MESH.09279105
12/14/1998	Memo to Rousseau re Biocomp Risk Assess Prolene	ETH.MESH.09279161	ETH.MESH.09279161
5/18/2010	Gynecare TVT Abbrevo Launch Planning Stage Gate PLT PPT Presentation.	Eth.Mesh.09294125	
5/18/2010	TVT Abbrevo Launch Planning Stage Gate PLT	ETH.MESH.09294125	ETH.MESH.09294125
12/2/1999	Memo to R. Rousseau re Biocompatibility Risk Assessment for Soft PROLENE Mesh	ETH.MESH.09346419	ETH.MESH.09346420
	TVT Prolene Digital Photograph	ETH.MESH.09479067	ETH.MESH.09479067
7/9/1992	Lindemann 7 year prolene explants images	ETH.MESH.09557798	ETH.MESH.09557818
10/1/1992	Muse lab notebook notes re GPC of Polypropylene	ETH.MESH.09557819	ETH.MESH.09557819

DOCUMENTS

10/15/1992	Seven Year Data for Ten Year Prolene Study: ERF 85-219	ETH.MESH.09557820	ETH.MESH.09557856
	Presentation: When the implant worries the body	ETH.MESH.09645766	ETH.MESH.09645779
	Invention Disclosure	ETH.MESH.09651393	ETH.MESH.09651401
	Meier LIGHTning project presentation	ETH.MESH.09651966	ETH.MESH.09651978
	Presentation: Today's vaginal implants do not consider the patients' biomechanical needs	ETH.MESH.09652185	ETH.MESH.09652190
1/13/2010	email transmitting absgtract of Jurgen Trzewik "Applied Biomechanics -- Meeting the Customer Demands."	ETH.MESH.09653077	ETH.MESH.09653079
	Presentation Uniaxial test - theoretical considerations	ETH.MESH.09654601	ETH.MESH.09654643
8/5/2009	Trzewik J email re Def. stress shielding	ETH.MESH.09655947	ETH.MESH.09655947
1/8/2009	Presentation: Biomechanical considerations	ETH.MESH.09656632	ETH.MESH.09656644
4/13/2010	Trzewik J email chain re laser cutting	ETH.MESH.09656790	ETH.MESH.09656795
	Internal chart from Ethicon researcher Spychaj's file stating the weight and pore size of Prolene mesh	Eth.Mesh.09671620	
	Material specification spreadsheet	ETH.MESH.09671620	ETH.MESH.09671620
6/18/2013	Issue Report	ETH.MESH.09729161	ETH.MESH.09729161
5/30/1985	Protocol for 10 year in vivo study for Prolene Sutures in	Eth.Mesh.09888068	
5/30/1985	Protocol for 10 year In Vivo Study	ETH.MESH.09888068	ETH.MESH.09888143
10/15/1992	Seven Year Data for Ten Year Prolene Study	ETH.MESH.09888187	ETH.MESH.09888223
	7 Year Data	Eth.Mesh.09888187	ETH.MESH.09888223
5/14/2001	TVT-O Design History Book 3 of y	ETH.MESH.09908346	ETH.MESH.09908660
	TVT-O Design History Book 3 of 7	Eth.Mesh.09908346	
5/8/2013	Biocompatibility Risk Assessment Report for the GYNECARE TVT Product Family.	Eth.Mesh.09909830	
5/8/2013	Biocompatibility Risk Assessment Report for Gynecare TVT Product Family	ETH.MESH.09909830	ETH.MESH.09909882
11/13/2008	Smith D memo: Things to consider as we assess next steps for a next generation sling	ETH.MESH.09911296	ETH.MESH.09911299
01/??/1998	Angelini, Byca, Montanino Gynecare Europena Marketing Plan	ETH.MESH.10183005	ETH.MESH.10183061
4/6/2011	Hoffman S email chain re 6 weeks into Abbrevo Launch	ETH.MESH.10224489	ETH.MESH.10224490
8/6/2011	Email re: 6 Weeks into Abbrevo Launch.	Eth.Mesh.10224489	
12/9/2010	Prine G email chain re TVT-Abbrevo Sales Literature and DVD now available	ETH.MESH.10237693	ETH.MESH.10237695
0/0/2010	Email discussing surgeon feedback for Abbrevo	Eth.Mesh.10237693	
4/6/2000	182-day intramuscular tissue reaction study conducted in rats.	Eth.Mesh.10282451	ETH.MESH.10282480

DOCUMENTS

4/10/2006	An evaluation of the Gynecare TVT Tension-free support for incontinence and Gynecare TVT Obturator system tension-free support for incontinence with laser cut mesh - Amendment 1	ETH.MESH.10302268	ETH.MESH.10302279
	Xavier Buchon - An evaluation of the application of the Gynecare TVT Obturator system tension-free support for incontinence with laser cut mesh	ETH.MESH.10372554	ETH.MESH.10372564
	TVT-S RMR Rev 2	ETH.MESH.10605402	ETH.MESH.10605419
8/22/2013	Hinoul request for meeting re TVT-S RMR followup	ETH.MESH.10606632	ETH.MESH.10606632
8/29/2013	Hackman L email chain re TVT-Secur RMR documents	ETH.MESH.10607066	ETH.MESH.10607084
3/19/2997	CER March 19 2007 Prosima	ETH.MESH.10623779	ETH.MESH.10623792
12/27/2006	Biocompatibility Risk Assessment	ETH.MESH.10624539	ETH.MESH.10624551
	Sunoco MSDS	ETH.MESH.10630809	ETH.MESH.10630813
10/19/1982	Prolene (polypropylene) Sutures: Suface additive study - Tissue Respoinse, rate - Pilot Study - Final Report	ETH.MESH.10645237	ETH.MESH.10645242
10/19/1983	PROLENE (Polypropylene) Sutures: Surface Additive Study - Tissue Response. Rats - Pilot	Eth.Mesh.10645237	
2/24/2006	Lamont D Memo re TVT Laser Cut Mesh (LCM) Risk Analysis Summary	ETH.MESH.10984358	ETH.MESH.10984359
		ETH.MESH.11298502	
10/2/2013	TVT-S RMR Rev 1	ETH.MESH.11335589	ETH.MESH.11335605
9/20/1988	2 Year Dog Study Interim Report	ETH.MESH.11336071	ETH.MESH.11336088
	2 Year Dog Study Interim Report	Eth.Mesh.11336071	ETH.MESH.11336088
8/10/1990	Five Year Data for Ten Year In Vivo Suture Study	ETH.MESH.11336165	ETH.MESH.11336177
	5 Year Data	Eth.Mesh.11336165	ETH.MESH.11336177
10/19/1992	Agarwal V memto to Cofone M re Interim report on physical testing	ETH.MESH.11336181	ETH.MESH.11336183
	Interim Report on the Physical Testing	Eth.Mesh.11336181	ETH.MESH.11336183
	Protocol of 10 year In vivo Dog Study	Eth.Mesh.11336184	ETH.MESH.11336259
	Seven Year Dog Sudy	ETH.MESH.11336184	ETH.MESH.11336338
8/10/1990	Five Year Report re Ten Year In Vivo Suture Study	ETH.MESH.11336474	ETH.MESH.11336487
	Risk Assessment Summary for Products in the Gynecare TVT Secur System - Revision Hx for 100146510	ETH.MESH.11353422	ETH.MESH.11353439
12/??/10	TVT Abbrevo Patient Brochure	ETH.MESH.11434264	ETH.MESH.11434272
1/1/2011	TVT Abbrevo Selling Guide	ETH.MESH.11434367	ETH.MESH.11434379
5/16/2011	Bernal O email chain re TVT Abbrevo Eval	ETH.MESH.11445930	ETH.MESH.11445931
0/0/2011	Email regarding Abbrevo marketing	Eth.Mesh.11445930	
	Analytical Characterization PPT Presentation	ETH.MESH.11488705	ETH.MESH.11488724
3/31/2011	Phillips K email re Prosima+M	ETH.MESH.11790162	ETH.MESH.11790162
	Analytical Chemistry Monthly Report	ETH.MESH.11921637	ETH.MESH.11921648
	Analytical Chemistry Monthly Report	ETH.MESH.11921649	ETH.MESH.11921659

DOCUMENTS

11/0/2008	Presentation: The future of surgical meshes: the industry's perspective	Eth.Mesh.1203957	
		eth.mesh.12288401	
8/10/1990	Ten Year In Vivo Suture Study - Five Year Report	ETH.MESH.12729337	ETH.MESH.12729350
10/10/1990	Five Year Data for Ten Year PROLENE Study	Eth.Mesh.12729337	ETH.MESH.12729350
9/30/1987	Ethicon Prolene study of human explants	Eth.Mesh.12831391	ETH.MESH.12831404
6/15/1982	Melveger Memo re Crack Depth in Explanted Porlene Polypropylene Sutures	ETH.MESH.12831405	ETH.MESH.12831406
11/12/1987	Prolene Explants Study Meeting Minutes.	Eth.Mesh.12831407	ETH.MESH.12831408
11/12/1987	Memo re Prolene Explants Study Meeting Minutes 10/08/1987	ETH.MESH.12831407	ETH.MESH.12831408
5/3/2013	Prosima CER	ETH.MESH.12897617	ETH.MESH.12897678
		eth.mesh.12922032	
9/30/1987	IR Microscopy of Explanted Prolene Received from Prof. R. Guidoin	ETH.MESH.13334286	ETH.MESH.13334299
9/17/2013	Hinoul email chain re TVT Secur CER for Risk analysis meetings	ETH.MESH.13456293	ETH.MESH.13456299
8/20/2013	Hackman L email chain re docs for TVT-S RMR	ETH.MESH.13574767	ETH.MESH.13574785
	DRM Prosima version 2	ETH.MESH.13650299	ETH.MESH.13650304
		ETH.MESH.14234628	
3/3/2004	Copy Review Submission Form - Inside Gynecare Vol II, #5	ETH.MESH.14416182	ETH.MESH.14416221
	Justification for Utilizing the Elasticity Test as the Elongation Requirements on TVT Laser Cut Mesh	ETH.MESH.14450438	ETH.MESH.14450442
??/??/1987	Prolene Explant Lab Notebook Pages and Images	ETH.MESH.15406846	ETH.MESH.15406856
	Prolene Explant Lab Notebook Pages and Images	Eth.Mesh.15406846	Eth.Mesh.15406999
N/A	Prolene Explant Lab Notebook Pages and Associated Documents	ETH.MESH.15406846	ETH.MESH.15406999
1/20/1988	List of Explants	ETH.MESH.15406978	
3/23/1983	Matlaga memo to Lunn re Prolene Microcracks	ETH.MESH.15955438	ETH.MESH.15955473
	Prolene Explant Lab Notebook Pages and Images	Eth.Mesh.15955438	Eth.Mesh.15955473
11/13/1984	Memo to McDivitt J re Fourier Transform-Infared Examination of Prolene Microcrack and Photo-Oxidized Polypropylene	ETH.MESH.15958336	ETH.MESH.15958395
	Prolene Explant Lab Notebook Pages and Images	Eth.Mesh.15958336	Eth.Mesh.15958469
3/17/1982	Microscopic Examination of Prolene Suture and Dacron Graft Returned for Norfolk Surgical Group, Ltd (human retrieval).	ETH.MESH.15958396	ETH.MESH.15958399
11/7/1984	Prolene Polypropylene Suture Explant from Dr. Drewes	Eth.Mesh.15958405	ETH.MESH.15958407
9/27/1984	Prolene 7 Year Explant ERF Accession #84-533.	Eth.Mesh.15958408	Eth.Mesh.15958409
3/25/1983	Examination of 5/0 and 6/0 Cardiovascular Prolene Sutures Explanted after 2 to 6 years Implantation.	ETH.MESH.15958410	ETH.MESH.15958432

DOCUMENTS

8/4/1984	Examination of Ends of PREP and Prolene Sutures Reported to have Broken in Animals.	Eth.Mesh.15958433	Eth.Mesh.15958444
3/11/1985	Prolene Microcrack Experiments	ETH.MESH.15958445	ETH.MESH.15958541
11/5/1984	Prolene Microcracking	ETH.MESH.15958452	ETH.MESH.15958469
	Prolene Explant Lab Notebook Pages and Images	Eth.Mesh.15958470	Eth.Mesh.15958477
	Prolene Explant Lab Notebook Pages and Images	Eth.Mesh.15958478	Eth.Mesh.15958524
	Prolene Explant Lab Notebook Pages and Images	ETH.MESH.15958478	ETH.MESH.15958480
	Explant Images	ETH.MESH.15958525	ETH.MESH.15958532
	Prolene Explant Lab Notebook Pages and Images	ETH.MESH.15984870	ETH.MESH.15984870
2/7/2008	Kahlson H email chain re Conversion to Laset Cut TVT	ETH.MESH.16416002	ETH.MESH.16416004
	Explant Images	ETH.MESH.17775693	ETH.MESH.17775734
		ETH.MESH.22007216	
		ETH.MESH.22007832	
7/6/2011	Email re: pore classification	Eth.Mesh.5337217	
	Chart re Prolene weight and pore size	Eth.Mesh.9671620	
	Marketing Brochure Pelvic Organ Prolapse in Women: It's Common. It's Treatable	ETH-00255	ETH-00255
??/??/06	GPS for Pelvic Floor Repair	ETH-00289	ETH-00294
??/??/04	Prolift IFU	ETH-00295	ETH-00300
1/22/2008	Lisa Memo re question for updated IFU	ETH-01754	ETH-01756
2/28/2005	Everett J Summary Memo for Revision C of the Gynecare PROLIFT Device Design Safety Assessment	ETH-03531	ETH-03567
2/28/2005	Everett Memo re Summary for Revision C of the Gynecare Prolift Device Safety Assessment	ETH-03534	ETH-03570
	PR602-003 Appendix VI - Device Design Safety Assessment Form	ETH-03558	ETH-03558
		ETH-03568	
4/7/2008	Pelekis Memo to Samon re Risk Assessment for Laser Ccutting of D'Art Gynemesh PS Implants	ETH-03883	ETH-03889
		ETH-05945	
		ETH-06043	
1/14/2005	Owens Clinical Expert Report Gynecare Prolift	ETH-07152	ETH-07158
		ETH-07247	
??/??/06	Stop coping. Start Living Patient Brochure	ETH-10187	ETH-10202
1/18/2005	Brown K email chain re Proposal for work with CBAT	ETH-18761	ETH-18763
	IFU illustrations	ETH-65881	ETH-65881
6/14/2006	Bonet G email chain re Mesh Microns	ETH-83454	ETH-83454
1/26/2006	Porosity Measurement of AMS Intepro Mesh	ETH-83788	ETH-83788
4/14/2006	Regina A email chain re TSM presentations	HMESH.ETH.00108021	HMESH.ETH.00108024
8/31/2009	Rauso J email chain Re shrinkage	HMESH.ETH.00110207	HMESH.ETH.00110208
6/12/2012	Fuchte L email re Ultrapro article in newspaper	HMESH.ETH.00129489	HMESH.ETH.00129490

DOCUMENTS

	Walther C ltt Quentin re Discussions with patent department	HMESH_ETH_00379723	HMESH_ETH_00379723
	Nylon MSDS	HMESH_ETH_00660369	HMESH_ETH_00660411
11/1/1988	Santonox R Antioxidant MSDS	N/A	N/A
6/26/2007	DLTDP MSDS	N/A	N/A
10/5/2010	DLTDP MSDS (2)	N/A	N/A
4/24/2012	Calcium Stearate MSDS	N/A	N/A
5/21/2013	Calcium Stearate MSDS (2)	N/A	N/A
	MSDS for Calcium Stearate	N/A	
	MSDS for Dilauralthiodipropionate (DLTDP)	N/A	
	MSDS for Santonox R	N/A	
	MSDS for Procol LA-10	N/A	
	MSDS for Copper phthalocyanate (CPC) Pigment	N/A	
	Sunoco MSDS 2006	N/A	
	Sunoco MSDS 2004	N/A	
	Marlex MSDS 2011	N/A	
	Marlex MSDS 2001, 2003, 2004, 2007, 2008	N/A	
	In Vitro degradation testing and related documents on polypropylene in collaboration with Dr. Russell Dunn	N/A	
6/22/2006	Gadot, H EMEA Launch Strategy		